In the Senate of the United States,

October 14, 1999.

Resolved, That the bill from the House of Representatives (H.R. 2990) entitled ''An Act to amend the Internal Revenue Code of 1986 to allow individuals greater access to health insurance through a health care tax deduction, a long-term care deduction, and other health-related tax incentives, to amend the Employee Retirement Income Security Act of 1974 to provide access to and choice in health care through association health plans, to amend the Public Health Service Act to create new pooling opportunities for small employers to obtain greater access to health coverage through HealthMarts; to amend title I of the Employee Retirement Income Security Act of 1974, title XXVII of the Public Health Service Act, and the Internal Revenue Code of 1986 to protect consumers in managed care plans and other health coverage; and for other purposes.'', do pass with the following

AMENDMENT:

Strike out all after the enacting clause and insert:

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the ''Patients' Bill of Rights Plus Act''.

(b) TABLE OF CONTENTS.—The table of contents for this Act is as follows:

TITLE I—PATIENTS' BILL OF RIGHTS

Subtitle A—Right to Advice and Care

SEC. 101. PATIENT RIGHT TO MEDICAL ADVICE AND CARE.

(a) IN GENERAL.—Part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1181 et seq.) is amended—

(1) by redesignating subpart C as subpart D; and

(2) by inserting after subpart B the following:

"Subpart C—Patient Right to Medical Advice and Care

"SEC. 721. PATIENT ACCESS TO EMERGENCY MEDICAL CARE.

"(a) COVERAGE OF EMERGENCY CARE.—

"(1) IN GENERAL.—To the extent that the group health plan (other than a fully insured group health plan) provides coverage for benefits consisting of emergency medical care (as defined in subsection (c)) or emergency ambulance services, except for items or services specifically excluded—

"(A) the plan shall provide coverage for benefits, without requiring preauthorization, for emergency medical screening examinations or emergency ambulance services, to the extent that a prudent layperson, who possesses an average knowledge of health and medicine, would determine such examinations or emergency ambulance services to be necessary to determine whether emergency medical care (as so defined) is necessary; and

"(B) the plan shall provide coverage for benefits, without requiring preauthorization, for additional emergency medical care to stabilize an emergency medical condition following an emergency medical screening examination (if de-

termined necessary under subparagraph (A)), pursuant to the definition of stabilize under section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

"(2) REIMBURSEMENT FOR CARE TO MAINTAIN MEDICAL STABILITY.—

"(A) IN GENERAL.—In the case of services provided to a participant or beneficiary by a nonparticipating provider in order to maintain the medical stability of the participant or beneficiary, the group health plan involved shall provide for reimbursement with respect to such services if—

"(i) coverage for services of the type furnished is available under the group health plan;

"(ii) the services were provided for care related to an emergency medical condition and in an emergency department in order to maintain the medical stability of the participant or beneficiary; and

"(iii) the nonparticipating provider contacted the plan regarding approval for such services.

"(B) FAILURE TO RESPOND.—If a group health plan fails to respond within 1 hours of being contacted in accordance with subparagraph (A)(iii), then the plan shall be liable for the cost of services provided by the nonparticipating provider in order to maintain the stability of the participant or beneficiary.

"(C) LIMITATION.—The liability of a group health plan to provide reimbursement under subparagraph (A) shall terminate when the plan has contacted the nonparticipating provider to arrange for discharge or transfer.

"(D) LIABILITY OF PARTICIPANT.—A participant or beneficiary shall not be liable for the costs of services to which subparagraph (A) in an amount that exceeds the amount of liability that would be incurred if the services were provided by a participating health care provider with prior authorization by the plan.

"(b) IN-NETWORK UNIFORM COSTS-SHARING AND OUT-OF-NETWORK CARE.—

"(1) IN-NETWORK UNIFORM COST-SHARING.—Nothing in this section shall be construed as preventing a group health plan (other than a fully insured group health plan) from imposing any form of

cost-sharing applicable to any participant or beneficiary (including coinsurance, copayments, deductibles, and any other charges) in relation to coverage for benefits described in subsection (a), if such form of cost-sharing is uniformly applied under such plan, with respect to similarly situated participants and beneficiaries, to all benefits consisting of emergency medical care (as defined in subsection (c)) provided to such similarly situated participants and beneficiaries under the plan, and such cost-sharing is disclosed in accordance with section 714.

"(2) OUT-OF-NETWORK CARE.—If a group health plan (other than a fully insured group health plan) provides any benefits with respect to emergency medical care (as defined in subsection (c)), the plan shall cover emergency medical care under the plan in a manner so that, if such care is provided to a participant or beneficiary by a nonparticipating health care provider, the participant or beneficiary is not liable for amounts that exceed any form of cost-sharing (including co-insurance, co-payments, deductibles, and any other charges) that would be incurred if the services were provided by a participating provider.

"(c) DEFINITION OF EMERGENCY MEDICAL CARE.—In this section:

"(1) IN GENERAL.—The term 'emergency medical care' means, with respect to a participant or beneficiary under a group health plan (other than a fully insured group health plan), covered inpatient and outpatient services that—

"(A) are furnished by any provider, including a nonparticipating provider, that is qualified to furnish such services; and

"(B) are needed to evaluate or stabilize (as such term is defined in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd)(e)(3)) an emergency medical condition (as defined in paragraph (2)).

"(2) EMERGENCY MEDICAL CONDITION.—The term 'emergency medical condition' means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in—

"(A) placing the health of the participant or beneficiary (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy,

"(B) serious impairment to bodily functions, or

"(C) serious dysfunction of any bodily organ or part.

"SEC. 722. OFFERING OF CHOICE OF COVERAGE OPTIONS.

"(a) REQUIREMENT.—

"(1) OFFERING OF POINT-OF-SERVICE COVERAGE OPTION.—Except as provided in paragraph (2), if a group health plan (other than a fully insured group health plan) provides coverage for benefits only through a defined set of participating health care professionals, the plan shall offer the participant the option to purchase point-of-service coverage (as defined in subsection (b)) for all such benefits for which coverage is otherwise so limited. Such option shall be made available to the participant at the time of enrollment under the plan and at such other times as the plan offers the participant a choice of coverage options.

"(2) EXCEPTION IN CASE OF LACK OF AVAILABILITY.—Paragraph (1) shall not apply with respect to a group health plan (other than a fully insured group health plan) if care relating to the point-of-service coverage would not be available and accessible to the participant with reasonable promptness (con-

sistent with section 1301(b)(4) of the Public Health Service Act (42 U.S.C. 300e(b)(4))).

"(b) POINT-OF-SERVICE COVERAGE DEFINED.—In this section, the term 'point-of-service coverage' means, with respect to benefits covered under a group health plan (other than a fully insured group health plan), coverage of such benefits when provided by a nonparticipating health care professional.

"(c) SMALL EMPLOYER EXEMPTION.—

"(1) IN GENERAL.—This section shall not apply to any group health plan (other than a fully insured group health plan) of a small employer.

"(2) SMALL EMPLOYER.—For purposes of paragraph (1), the term 'small employer' means, in connection with a group health plan (other than a fully insured group health plan) with respect to a calendar year and a plan year, an employer who employed an average of at least 2 but not more than 50 employees on business days during the preceding calendar year and who employs at least 2 employees on the first day of the plan year. For purposes of this paragraph, the provisions of subparagraph (C) of section 712(c)(1) shall apply in determining employer size.

"(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed—

"(1) as requiring coverage for benefits for a particular type of health care professional;

"(2) as requiring an employer to pay any costs as a result of this section or to make equal contributions with respect to different health coverage options;

"(3) as preventing a group health plan (other than a fully insured group health plan) from imposing higher premiums or cost-sharing on a participant for the exercise of a point-of-service coverage option; or

"(4) to require that a group health plan (other than a fully insured group health plan) include coverage of health care professionals that the plan excludes because of fraud, quality of care, or other similar reasons with respect to such professionals.

"SEC. 723. PATIENT ACCESS TO OBSTETRIC AND GYNECOLOGICAL CARE.

"(a) GENERAL RIGHTS.—

"(1) WAIVER OF PLAN REFERRAL REQUIREMENT.—If a group health plan described in subsection (b) requires a referral to obtain coverage for specialty care, the plan shall waive the referral requirement in the case of a female participant or beneficiary who seeks coverage for obstetrical care and related follow-

up obstetrical care or routine gynecological care (such as preventive gynecological care).

"(2) RELATED ROUTINE CARE.—With respect to a participant or beneficiary described in paragraph (1), a group health plan described in subsection (b) shall treat the ordering of other routine care that is related to routine gynecologic care, by a physician who specializes in obstetrics and gynecology as the authorization of the primary care provider for such other care.

"(b) APPLICATION OF SECTION.—A group health plan described in this subsection is a group health plan (other than a fully insured group health plan), that—

"(1) provides coverage for obstetric care (such as pregnancy-related services) or routine gynecologic care (such as preventive women's health examinations); and

"(2) requires the designation by a participant or beneficiary of a participating primary care provider who is not a physician who specializes in obstetrics or gynecology.

"(c) RULES OF CONSTRUCTION.—Nothing in this section shall be construed—

"(1) as waiving any coverage requirement relating to medical necessity or appropriateness with re-

spect to the coverage of obstetric or gynecologic care described in subsection (a);

"(2) to preclude the plan from requiring that the physician who specializes in obstetrics or gynecology notify the designated primary care provider or the plan of treatment decisions;

"(3) to preclude a group health plan from allowing health care professionals other than physicians to provide routine obstetric or routine gynecologic care; or

"(4) to preclude a group health plan from permitting a physician who specializes in obstetrics and gynecology from being a primary care provider under the plan.

"SEC. 724. PATIENT ACCESS TO PEDIATRIC CARE.

"(a) IN GENERAL.—In the case of a group health plan (other than a fully insured group health plan) that provides coverage for routine pediatric care and that requires the designation by a participant or beneficiary of a participating primary care provider, if the designated primary care provider is not a physician who specializes in pediatrics—

"(1) the plan may not require authorization or referral by the primary care provider in order for a

participant or beneficiary to obtain coverage for routine pediatric care; and

"(2) the plan shall treat the ordering of other routine care related to routine pediatric care by such a specialist as having been authorized by the designated primary care provider.

"(b) RULES OF CONSTRUCTION.—Nothing in subsection (a) shall be construed—

"(1) as waiving any coverage requirement relating to medical necessity or appropriateness with respect to the coverage of any pediatric care provided to, or ordered for, a participant or beneficiary;

"(2) to preclude a group health plan from requiring that a specialist described in subsection (a) notify the designated primary care provider or the plan of treatment decisions; or

"(3) to preclude a group health plan from allowing health care professionals other than physicians to provide routine pediatric care.

"SEC. 725. TIMELY ACCESS TO SPECIALISTS.

"(a) TIMELY ACCESS.—

"(1) IN GENERAL.—A group health plan (other than a fully insured group health plan) shall ensure that participants and beneficiaries have timely, in accordance with the medical exigencies of the case, ac-

cess to primary and specialty health care professionals who are appropriate to the condition of the participant or beneficiary, when such care is covered under the plan. Such access may be provided through contractual arrangements with specialized providers outside of the network of the plan.

"(2) RULE OF CONSTRUCTION.—Nothing in paragraph (1) shall be construed—

"(A) to require the coverage under a group health plan of particular benefits or services or to prohibit a plan from including providers only to the extent necessary to meet the needs of the plan's participants or beneficiaries or from establishing any measure designed to maintain quality and control costs consistent with the responsibilities of the plan; or

"(B) to override any State licensure or scope-of-practice law.

"(b) TREATMENT PLANS.—

"(1) IN GENERAL.—Nothing in this section shall be construed to prohibit a group health plan (other than a fully insured group health plan) from requiring that specialty care be provided pursuant to a treatment plan so long as the treatment plan is—

"(A) developed by the specialist, in consultation with the case manager or primary care provider, and the participant or beneficiary;

"(B) approved by the plan in a timely manner in accordance with the medical exigencies of the case; and

"(C) in accordance with the applicable quality assurance and utilization review standards of the plan.

"(2) NOTIFICATION.—Nothing in paragraph (1) shall be construed as prohibiting a plan from requiring the specialist to provide the case manager or primary care provider with regular updates on the specialty care provided, as well as all other necessary medical information.

"(c) REFERRALS.—Nothing in this section shall be construed to prohibit a plan from requiring an authorization by the case manager or primary care provider of the participant or beneficiary in order to obtain coverage for specialty services so long as such authorization is for an adequate number of referrals.

"(d) SPECIALTY CARE DEFINED.—For purposes of this subsection, the term 'specialty care' means, with respect to a condition, care and treatment provided by a health care practitioner, facility, or center (such as a center of excel-

lence) that has adequate expertise (including age-appropriate expertise) through appropriate training and experience.

"SEC. 726. CONTINUITY OF CARE.

"(a) IN GENERAL.—

"(1) TERMINATION OF PROVIDER.—If a contract between a group health plan (other than a fully insured group health plan) and a health care provider is terminated (as defined in paragraph (2)), or benefits or coverage provided by a health care provider are terminated because of a change in the terms of provider participation in such group health plan, and an individual who is a participant or beneficiary in the plan is undergoing a course of treatment from the provider at the time of such termination, the plan shall—

"(A) notify the individual on a timely basis of such termination;

"(B) provide the individual with an opportunity to notify the plan of a need for transitional care; and

"(C) in the case of termination described in paragraph (2), (3), or (4) of subsection (b), and subject to subsection (c), permit the individual to continue or be covered with respect to the course

of treatment with the provider's consent during a transitional period (as provided under subsection (b)).

"(2) TERMINATED.—In this section, the term 'terminated' includes, with respect to a contract, the expiration or nonrenewal of the contract by the group health plan, but does not include a termination of the contract by the plan for failure to meet applicable quality standards or for fraud.

"(3) CONTRACTS.—For purposes of this section, the term 'contract between a group health plan (other than a fully insured group health plan) and a health care provider' shall include a contract between such a plan and an organized network of providers.

"(b) TRANSITIONAL PERIOD.—

"(1) GENERAL RULE.—Except as provided in paragraph (3), the transitional period under this subsection shall permit the participant or beneficiary to extend the coverage involved for up to 90 days from the date of the notice described in subsection (a)(1)(A) of the provider's termination.

"(2) INSTITUTIONAL CARE.—Subject to paragraph (1), the transitional period under this subsection for institutional or inpatient care from a provider shall extend until the discharge or termination

of the period of institutionalization and also shall include institutional care provided within a reasonable time of the date of termination of the provider status if the care was scheduled before the date of the announcement of the termination of the provider status under subsection (a)(1)(A) or if the individual on such date was on an established waiting list or otherwise scheduled to have such care.

"(3) PREGNANCY.—Notwithstanding paragraph (1), if—

"(A) a participant or beneficiary has entered the second trimester of pregnancy at the time of a provider's termination of participation; and

"(B) the provider was treating the pregnancy before the date of the termination;

the transitional period under this subsection with respect to provider's treatment of the pregnancy shall extend through the provision of post-partum care directly related to the delivery.

"(4) TERMINAL ILLNESS.—Notwithstanding paragraph (1), if—

"(A) a participant or beneficiary was determined to be terminally ill (as determined under section 1861(dd)(3)(A) of the Social Security

Act) prior to a provider's termination of participation; and

"(B) the provider was treating the terminal illness before the date of termination;

the transitional period under this subsection shall be for care directly related to the treatment of the terminal illness and shall extend for the remainder of the individual's life for such care.

"(c) PERMISSIBLE TERMS AND CONDITIONS.—A group health plan (other than a fully insured group health plan) may condition coverage of continued treatment by a provider under subsection (a)(1)(C) upon the provider agreeing to the following terms and conditions:

"(1) The provider agrees to accept reimbursement from the plan and individual involved (with respect to cost-sharing) at the rates applicable prior to the start of the transitional period as payment in full (or at the rates applicable under the replacement plan after the date of the termination of the contract with the group health plan) and not to impose cost-sharing with respect to the individual in an amount that would exceed the cost-sharing that could have been imposed if the contract referred to in subsection (a)(1) had not been terminated.

"(2) The provider agrees to adhere to the quality assurance standards of the plan responsible for payment under paragraph (1) and to provide to such plan necessary medical information related to the care provided.

"(3) The provider agrees otherwise to adhere to such plan's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan.

"(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to require the coverage of benefits which would not have been covered if the provider involved remained a participating provider.

"(e) DEFINITION.—In this section, the term 'health care provider' or 'provider' means—

"(1) any individual who is engaged in the delivery of health care services in a State and who is required by State law or regulation to be licensed or certified by the State to engage in the delivery of such services in the State; and

"(2) any entity that is engaged in the delivery of health care services in a State and that, if it is required by State law or regulation to be licensed or

certified by the State to engage in the delivery of such services in the State, is so licensed.

"(f) COMPREHENSIVE STUDY OF COST, QUALITY AND COORDINATION OF COVERAGE FOR PATIENTS AT THE END OF LIFE.—

"(1) STUDY BY THE MEDICARE PAYMENT ADVISORY COMMISSION.—The Medicare Payment Advisory Commission shall conduct a study of the costs and patterns of care for persons with serious and complex conditions and the possibilities of improving upon that care to the degree it is triggered by the current category of terminally ill as such term is used for purposes of section 1861(dd) of the Social Security Act (relating to hospice benefits) or of utilizing care in other payment settings in Medicare.

"(2) AGENCY FOR HEALTH CARE POLICY AND RESEARCH.—The Agency for Health Care Policy and Research shall conduct studies of the possible thresholds for major conditions causing serious and complex illness, their administrative parameters and feasibility, and their impact upon costs and quality.

"(3) HEALTH CARE FINANCING ADMINISTRATION.—The Health Care Financing Administration shall conduct studies of the merits of applying similar thresholds in Medicare+Choice programs, including

adapting risk adjustment methods to account for this category.

"(4) INITIAL REPORT.—

"(A) IN GENERAL.—Not later than 12 months after the date of enactment of this section, the Medicare Payment Advisory Commission and the Agency for Health Care Policy and Research shall each prepare and submit to the Committee on Health, Education, Labor and Pensions of the Senate a report concerning the results of the studies conducted under paragraphs (1) and (2), respectively.

"(B) COPY TO SECRETARY.—Concurrent with the submission of the reports under subparagraph (A), the Medicare Payment Advisory Commission and the Agency for health Care Policy and Research shall transmit a copy of the reports under such subparagraph to the Secretary.

"(5) FINAL REPORT.—

"(A) CONTRACT WITH INSTITUTE OF MEDICINE.—Not later than 1 year after the submission of the reports under paragraph (4), the Secretary of Health and Human Services shall contract with the Institute of Medicine to conduct a study of the practices and their effects arising

from the utilization of the category "serious and complex" illness.

"(B) REPORT.—Not later than 1 year after the date of the execution of the contract referred to in subparagraph (A), the Institute of Medicine shall prepare and submit to the Committee on Health, Education, Labor and Pensions of the Senate a report concerning the study conducted pursuant to such contract.

"(6) FUNDING.—From funds appropriated to the Department of Health and Human Services, the Secretary of Health and Human Services shall make available such funds as the Secretary determines is necessary to carry out this subsection.

"SEC. 727. PROTECTION OF PATIENT-PROVIDER COMMUNICATIONS.

"(a) IN GENERAL.—Subject to subsection (b), a group health plan (other than a fully insured group health plan and in relation to a participant or beneficiary) shall not prohibit or otherwise restrict a health care professional from advising such a participant or beneficiary who is a patient of the professional about the health status of the participant or beneficiary or medical care or treatment for the condition or disease of the participant or beneficiary, regardless of whether coverage for such care or treatment are provided

under the contract, if the professional is acting within the lawful scope of practice.

"(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as requiring a group health plan (other than a fully insured group health plan) to provide specific benefits under the terms of such plan.

"SEC. 728. PATIENT'S RIGHT TO PRESCRIPTION DRUGS.

"To the extent that a group health plan (other than a fully insured group health plan) provides coverage for benefits with respect to prescription drugs, and limits such coverage to drugs included in a formulary, the plan shall—

"(1) ensure the participation of physicians and pharmacists in developing and reviewing such formulary; and

"(2) in accordance with the applicable quality assurance and utilization review standards of the plan, provide for exceptions from the formulary limitation when a non-formulary alternative is medically necessary and appropriate.

"SEC. 729. SELF-PAYMENT FOR BEHAVIORAL HEALTH CARE SERVICES.

"(a) IN GENERAL.—A group health plan (other than a fully insured group health plan) may not—

"(1) prohibit or otherwise discourage a participant or beneficiary from self-paying for behavioral

health care services once the plan has denied coverage for such services; or

"(2) terminate a health care provider because such provider permits participants or beneficiaries to self-pay for behavioral health care services—

"(A) that are not otherwise covered under the plan; or

"(B) for which the group health plan provides limited coverage, to the extent that the group health plan denies coverage of the services.

"(b) RULE OF CONSTRUCTION.—Nothing in subsection (a)(2)(B) shall be construed as prohibiting a group health plan from terminating a contract with a health care provider for failure to meet applicable quality standards or for fraud.

"SEC. 730. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CANCER CLINICAL TRIALS.

"(a) COVERAGE.—

"(1) IN GENERAL.—If a group health plan (other than a fully insured group health plan) provides coverage to a qualified individual (as defined in subsection (b)), the plan—

"(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);

"(B) subject to subsections (b), (c), and (d) may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and

"(C) may not discriminate against the individual on the basis of the participant's or beneficiaries participation in such trial.

"(2) EXCLUSION OF CERTAIN COSTS.—For purposes of paragraph (1)(B), routine patient costs do not include the cost of the tests or measurements conducted primarily for the purpose of the clinical trial involved.

"(3) USE OF IN-NETWORK PROVIDERS.—If one or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed as preventing a plan from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial.

"(b) QUALIFIED INDIVIDUAL DEFINED.—For purposes of subsection (a), the term "qualified individual" means an individual who is a participant or beneficiary in a group health plan and who meets the following conditions:

"(1)(A) The individual has been diagnosed with cancer for which no standard treatment is effective.

"(B) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of such illness.

"(C) The individual's participation in the trial offers meaningful potential for significant clinical benefit for the individual.

"(2) Either—

"(A) the referring physician is a participating health care professional and has concluded that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1); or

"(B) the participant or beneficiary provides medical and scientific information establishing that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1).

"(c) PAYMENT.—

"(1) IN GENERAL.—Under this section a group health plan (other than a fully insured group health plan) shall provide for payment for routine patient

costs described in subsection (a)(2) but is not required to pay for costs of items and services that are reasonably expected to be paid for by the sponsors of an approved clinical trial.

"(2) STANDARDS FOR DETERMINING ROUTINE PATIENT COSTS ASSOCIATED WITH CLINICAL TRIAL PARTICIPATION.—

"(A) IN GENERAL.—The Secretary shall establish, on an expedited basis and using a negotiated rulemaking process under subchapter III of chapter 5 of title 5, United States Code, standards relating to the coverage of routine patient costs for individuals participating in clinical trials that group health plans must meet under this section.

"(B) FACTORS.—In establishing routine patient cost standards under subparagraph (A), the Secretary shall consult with interested parties and take into account —

"(i) quality of patient care;

"(ii) routine patient care costs versus costs associated with the conduct of clinical trials, including unanticipated patient care costs as a result of participation in clinical trials; and

"(iii) previous and on-going studies relating to patient care costs associated with participation in clinical trials.

"(C) PUBLICATION OF NOTICE.—In carrying out the rulemaking process under this paragraph, the Secretary, after consultation with organizations representing cancer patients, health care practitioners, medical researchers, employers, group health plans, manufacturers of drugs, biologics and medical devices, medical economists, hospitals, and other interested parties, shall publish notice provided for under section 564(a) of title 5, United States Code, by not later than 45 days after the date of the enactment of this section.

"(D) TARGET DATE FOR PUBLICATION OF RULE.—As part of the notice under subparagraph (C), and for purposes of this paragraph, the 'target date for publication' (referred to in section 564(a)(5) of such title 5) shall be June 30, 2000.

"(E) ABBREVIATED PERIOD FOR SUBMISSION OF COMMENTS.—In applying section 564(c) of such title 5 under this paragraph, '15 days' shall be substituted for '30 days'.

"(F) APPOINTMENT OF NEGOTIATED RULEMAKING COMMITTEE AND FACILITATOR.—The Secretary shall provide for—

"(i) the appointment of a negotiated rulemaking committee under section 565(a) of such title 5 by not later than 30 days after the end of the comment period provided for under section 564(c) of such title 5 (as shortened under subparagraph (E)), and

"(ii) the nomination of a facilitator under section 566(c) of such title 5 by not later than 10 days after the date of appointment of the committee.

"(G) PRELIMINARY COMMITTEE REPORT.—The negotiated rulemaking committee appointed under subparagraph (F) shall report to the Secretary, by not later than March 29, 2000, regarding the committee's progress on achieving a consensus with regard to the rulemaking proceeding and whether such consensus is likely to occur before 1 month before the target date for publication of the rule. If the committee reports that the committee has failed to make significant progress towards such consensus or is unlikely to

reach such consensus by the target date, the Secretary may terminate such process and provide for the publication of a rule under this paragraph through such other methods as the Secretary may provide.

"(H) FINAL COMMITTEE REPORT.—If the committee is not terminated under subparagraph (G), the rulemaking committee shall submit a report containing a proposed rule by not later than 1 month before the target date of publication.

"(I) FINAL EFFECT.—The Secretary shall publish a rule under this paragraph in the Federal Register by not later than the target date of publication.

"(J) PUBLICATION OF RULE AFTER PUBLIC COMMENT.—The Secretary shall provide for consideration of such comments and republication of such rule by not later than 1 year after the target date of publication.

"(K) EFFECTIVE DATE.—The provisions of this paragraph shall apply to group health plans (other than a fully insured group health plan) for plan years beginning on or after January 1, 2001.

"(3) PAYMENT RATE.—In the case of covered items and services provided by—

"(A) a participating provider, the payment rate shall be at the agreed upon rate, or

"(B) a nonparticipating provider, the payment rate shall be at the rate the plan would normally pay for comparable services under subparagraph (A).

"(d) APPROVED CLINICAL TRIAL DEFINED.—

"(1) IN GENERAL.—In this section, the term 'approved clinical trial' means a cancer clinical research study or cancer clinical investigation approved and funded (which may include funding through in-kind contributions) by one or more of the following:

"(A) The National Institutes of Health.

"(B) A cooperative group or center of the National Institutes of Health.

"(C) Either of the following if the conditions described in paragraph (2) are met:

"(i) The Department of Veterans Affairs.

"(ii) The Department of Defense.

"(2) CONDITIONS FOR DEPARTMENTS.—The conditions described in this paragraph, for a study or investigation conducted by a Department, are that the

study or investigation has been reviewed and approved through a system of peer review that the Secretary determines—

"(A) to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health, and

"(B) assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

"(e) CONSTRUCTION.—Nothing in this section shall be construed to limit a plan's coverage with respect to clinical trials.

"(f) PLAN SATISFACTION OF CERTAIN REQUIREMENTS; RESPONSIBILITIES OF FIDUCIARIES.—

"(1) IN GENERAL.—For purposes of this section, insofar as a group health plan provides benefits in the form of health insurance coverage through a health insurance issuer, the plan shall be treated as meeting the requirements of this section with respect to such benefits and not be considered as failing to meet such requirements because of a failure of the issuer to meet such requirements so long as the plan sponsor or its representatives did not cause such failure by the issuer.

"(2) CONSTRUCTION.—Nothing in this section shall be construed to affect or modify the responsibilities of the fiduciaries of a group health plan under part 4 of subtitle B.

"(g) STUDY AND REPORT.—

"(1) STUDY.—The Secretary shall study the impact on group health plans for covering routine patient care costs for individuals who are entitled to benefits under this section and who are enrolled in an approved cancer clinical trial program.

"(2) REPORT TO CONGRESS.—Not later than January 1, 2005, the Secretary shall submit a report to Congress that contains an assessment of—

"(A) any incremental cost to group health plans resulting from the provisions of this section;

"(B) a projection of expenditures to such plans resulting from this section; and

"(C) any impact on premiums resulting from this section.

"SEC. 730A. PROHIBITING DISCRIMINATION AGAINST PROVIDERS.

"(a) IN GENERAL.—A group health plan (other than a fully insured group health plan) shall not discriminate with respect to participation or indemnification as to any

provider who is acting within the scope of the provider's license or certification under applicable State law, solely on the basis of such license or certification. This subsection shall not be construed as requiring the coverage under a plan of particular benefits or services or to prohibit a plan from including providers only to the extent necessary to meet the needs of the plan's participants and beneficiaries or from establishing any measure designed to maintain quality and control costs consistent with the responsibilities of the plan.

"(b) NO REQUIREMENT FOR ANY WILLING PROVIDER.—Nothing in this section shall be construed as requiring a group health plan that offers network coverage to include for participation every willing provider or health professional who meets the terms and conditions of the plan.

"SEC. 730B. GENERALLY APPLICABLE PROVISION.

"In the case of a group health plan that provides benefits under 2 or more coverage options, the requirements of this subpart shall apply separately with respect to each coverage option.".

(b) RULE WITH RESPECT TO CERTAIN PLANS.—

(1) IN GENERAL.—Notwithstanding any other provision of law, health insurance issuers may offer, and eligible individuals may purchase, high deductible health plans described in section 220(c)(2)(A) of

the Internal Revenue Code of 1986. Effective for the 4-year period beginning on the date of the enactment of this Act, such health plans shall not be required to provide payment for any health care items or services that are exempt from the plan's deductible.

(2) EXISTING STATE LAWS.—A State law relating to payment for health care items and services in effect on the date of enactment of this Act that is preempted under paragraph (1), shall not apply to high deductible health plans after the expiration of the 4-year period described in such paragraph unless the State reenacts such law after such period.

(c) DEFINITION.—Section 733(a) of the Employee Retirement Income Security Act of 1974 (42 U.S.C. 1191(a)) is amended by adding at the end the following:

"(3) FULLY INSURED GROUP HEALTH PLAN.—The term 'fully insured group health plan' means a group health plan where benefits under the plan are provided pursuant to the terms of an arrangement between a group health plan and a health insurance issuer and are guaranteed by the health insurance issuer under a contract or policy of insurance.".

(d) CONFORMING AMENDMENT.—The table of contents in section 1 of such Act is amended—

(1) in the item relating to subpart C, by striking "Subpart C" and inserting "Subpart D"; and

(2) by adding at the end of the items relating to subpart B of part 7 of subtitle B of title I of such Act the following new items:

SEC. 102. CONFORMING AMENDMENT TO THE INTERNAL REVENUE CODE OF 1986.

(a) IN GENERAL.—Chapter 100 of the Internal Revenue Code of 1986 is amended—

(1) by redesignating subchapter C as subchapter D; and

(2) by inserting after subchapter B the following:

"Subchapter C—Patient Right to Medical Advice and Care

"SEC. 9821. PATIENT ACCESS TO EMERGENCY MEDICAL CARE.

"(a) COVERAGE OF EMERGENCY CARE.—

"(1) IN GENERAL.—To the extent that the group health plan (other than a fully insured group health plan) provides coverage for benefits consisting of emergency medical care (as defined in subsection (c)) or emergency ambulance services, except for items or services specifically excluded—

"(A) the plan shall provide coverage for benefits, without requiring preauthorization, for emergency medical screening examinations or emergency ambulance services, to the extent that a prudent layperson, who possesses an average knowledge of health and medicine, would determine such examinations or emergency ambulance services to be necessary to determine whether emergency medical care (as so defined) is necessary; and

"(B) the plan shall provide coverage for benefits, without requiring preauthorization, for additional emergency medical care to stabilize an emergency medical condition following an

emergency medical screening examination (if determined necessary under subparagraph (A)), pursuant to the definition of stabilize under section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd(e)(3)).

"(2) REIMBURSEMENT FOR CARE TO MAINTAIN MEDICAL STABILITY.—

"(A) IN GENERAL.—In the case of services provided to a participant or beneficiary by a nonparticipating provider in order to maintain the medical stability of the participant or beneficiary, the group health plan involved shall provide for reimbursement with respect to such services if—

"(i) coverage for services of the type furnished is available under the group health plan;

"(ii) the services were provided for care related to an emergency medical condition and in an emergency department in order to maintain the medical stability of the participant or beneficiary; and

"(iii) the nonparticipating provider contacted the plan regarding approval for such services.

"(B) FAILURE TO RESPOND.—If a group health plan fails to respond within 1 hours of being contacted in accordance with subparagraph (A)(iii), then the plan shall be liable for the cost of services provided by the nonparticipating provider in order to maintain the stability of the participant or beneficiary.

"(C) LIMITATION.—The liability of a group health plan to provide reimbursement under subparagraph (A) shall terminate when the plan has contacted the nonparticipating provider to arrange for discharge or transfer.

"(D) LIABILITY OF PARTICIPANT.—A participant or beneficiary shall not be liable for the costs of services to which subparagraph (A) in an amount that exceeds the amount of liability that would be incurred if the services were provided by a participating health care provider with prior authorization by the plan.

"(b) IN-NETWORK UNIFORM COSTS-SHARING AND OUT-OF-NETWORK CARE.—

"(1) IN-NETWORK UNIFORM COST-SHARING.—Nothing in this section shall be construed as preventing a group health plan (other than a fully insured group health plan) from imposing any form of

cost-sharing applicable to any participant or beneficiary (including coinsurance, copayments, deductibles, and any other charges) in relation to coverage for benefits described in subsection (a), if such form of cost-sharing is uniformly applied under such plan, with respect to similarly situated participants and beneficiaries, to all benefits consisting of emergency medical care (as defined in subsection (c)) provided to such similarly situated participants and beneficiaries under the plan, and such cost-sharing is disclosed in accordance with section 9814.

"(2) OUT-OF-NETWORK CARE.—If a group health plan (other than a fully insured group health plan) provides any benefits with respect to emergency medical care (as defined in subsection (c)), the plan shall cover emergency medical care under the plan in a manner so that, if such care is provided to a participant or beneficiary by a nonparticipating health care provider, the participant or beneficiary is not liable for amounts that exceed any form of cost-sharing (including coinsurance, copayments, deductibles, and any other charges) that would be incurred if the services were provided by a participating provider.

"(c) DEFINITION OF EMERGENCY MEDICAL CARE.—In this section:

"(1) IN GENERAL.—The term 'emergency medical care' means, with respect to a participant or beneficiary under a group health plan (other than a fully insured group health plan), covered inpatient and outpatient services that—

"(A) are furnished by any provider, including a nonparticipating provider, that is qualified to furnish such services; and

"(B) are needed to evaluate or stabilize (as such term is defined in section 1867(e)(3) of the Social Security Act (42 U.S.C. 1395dd)(e)(3)) an emergency medical condition (as defined in paragraph (2)).

"(2) EMERGENCY MEDICAL CONDITION.—The term 'emergency medical condition' means a medical condition manifesting itself by acute symptoms of sufficient severity (including severe pain) such that a prudent layperson, who possesses an average knowledge of health and medicine, could reasonably expect the absence of immediate medical attention to result in—

"(A) placing the health of the participant or beneficiary (or, with respect to a pregnant woman, the health of the woman or her unborn child) in serious jeopardy,

"(B) serious impairment to bodily functions, or

"(C) serious dysfunction of any bodily organ or part.

"SEC. 9822. OFFERING OF CHOICE OF COVERAGE OPTIONS.

"(a) REQUIREMENT.—

"(1) OFFERING OF POINT-OF-SERVICE COVERAGE OPTION.—Except as provided in paragraph (2), if a group health plan (other than a fully insured group health plan) provides coverage for benefits only through a defined set of participating health care professionals, the plan shall offer the participant the option to purchase point-of-service coverage (as defined in subsection (b)) for all such benefits for which coverage is otherwise so limited. Such option shall be made available to the participant at the time of enrollment under the plan and at such other times as the plan offers the participant a choice of coverage options.

"(2) EXCEPTION IN CASE OF LACK OF AVAILABILITY.—Paragraph (1) shall not apply with respect to a group health plan (other than a fully insured group health plan) if care relating to the point-of-service coverage would not be available and accessible to the participant with reasonable promptness (con-

sistent with section 1301(b)(4) of the Public Health Service Act (42 U.S.C. 300e(b)(4))).

"(b) POINT-OF-SERVICE COVERAGE DEFINED.—In this section, the term 'point-of-service coverage' means, with respect to benefits covered under a group health plan (other than a fully insured group health plan), coverage of such benefits when provided by a nonparticipating health care professional.

"(c) SMALL EMPLOYER EXEMPTION.—

"(1) IN GENERAL.—This section shall not apply to any group health plan (other than a fully insured group health plan) of a small employer.

"(2) SMALL EMPLOYER.—For purposes of paragraph (1), the term 'small employer' means, in connection with a group health plan (other than a fully insured group health plan) with respect to a calendar year and a plan year, an employer who employed an average of at least 2 but not more than 50 employees on business days during the preceding calendar year and who employs at least 2 employees on the first day of the plan year. For purposes of this paragraph, the provisions of subparagraph (C) of section 4980D(d)(2) shall apply in determining employer size.

"(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed—

"(1) as requiring coverage for benefits for a particular type of health care professional;

"(2) as requiring an employer to pay any costs as a result of this section or to make equal contributions with respect to different health coverage options;

"(3) as preventing a group health plan (other than a fully insured group health plan) from imposing higher premiums or cost-sharing on a participant for the exercise of a point-of-service coverage option; or

"(4) to require that a group health plan (other than a fully insured group health plan) include coverage of health care professionals that the plan excludes because of fraud, quality of care, or other similar reasons with respect to such professionals.

"SEC. 9823. PATIENT ACCESS TO OBSTETRIC AND GYNECOLOGICAL CARE.

"(a) GENERAL RIGHTS.—

"(1) WAIVER OF PLAN REFERRAL REQUIREMENT.—If a group health plan described in subsection (b) requires a referral to obtain coverage for specialty care, the plan shall waive the referral requirement in the case of a female participant or beneficiary who

seeks coverage for obstetrical care and related follow-up obstetrical care or routine gynecological care (such as preventive gynecological care).

"(2) RELATED ROUTINE CARE.—With respect to a participant or beneficiary described in paragraph (1), a group health plan described in subsection (b) shall treat the ordering of other routine care that is related to routine gynecologic care, by a physician who specializes in obstetrics and gynecology as the authorization of the primary care provider for such other care.

"(b) APPLICATION OF SECTION.—A group health plan described in this subsection is a group health plan (other than a fully insured group health plan), that—

"(1) provides coverage for obstetric care (such as pregnancy-related services) or routine gynecologic care (such as preventive women's health examinations); and

"(2) requires the designation by a participant or beneficiary of a participating primary care provider who is not a physician who specializes in obstetrics or gynecology.

"(c) RULES OF CONSTRUCTION.—Nothing in this section shall be construed—

"(1) as waiving any coverage requirement relating to medical necessity or appropriateness with respect to the coverage of obstetric or gynecologic care described in subsection (a);

"(2) to preclude the plan from requiring that the physician who specializes in obstetrics or gynecology notify the designated primary care provider or the plan of treatment decisions;

"(3) to preclude a group health plan from allowing health care professionals other than physicians to provide routine obstetric or routine gynecologic care; or

"(4) to preclude a group health plan from permitting a physician who specializes in obstetrics and gynecology from being a primary care provider under the plan.

"SEC. 9824. PATIENT ACCESS TO PEDIATRIC CARE.

"(a) IN GENERAL.—In the case of a group health plan (other than a fully insured group health plan) that provides coverage for routine pediatric care and that requires the designation by a participant or beneficiary of a participating primary care provider, if the designated primary care provider is not a physician who specializes in pediatrics—

"(1) the plan may not require authorization or referral by the primary care provider in order for a participant or beneficiary to obtain coverage for routine pediatric care; and

"(2) the plan shall treat the ordering of other routine care related to routine pediatric care by such a specialist as having been authorized by the designated primary care provider.

"(b) RULES OF CONSTRUCTION.—Nothing in subsection (a) shall be construed—

"(1) as waiving any coverage requirement relating to medical necessity or appropriateness with respect to the coverage of any pediatric care provided to, or ordered for, a participant or beneficiary;

"(2) to preclude a group health plan from requiring that a specialist described in subsection (a) notify the designated primary care provider or the plan of treatment decisions; or

"(3) to preclude a group health plan from allowing health care professionals other than physicians to provide routine pediatric care.

"SEC. 9825. TIMELY ACCESS TO SPECIALISTS.

"(a) TIMELY ACCESS.—

"(1) IN GENERAL.—A group health plan (other than a fully insured group health plan) shall ensure

that participants and beneficiaries have timely, in accordance with the medical exigencies of the case, access to primary and specialty health care professionals who are appropriate to the condition of the participant or beneficiary, when such care is covered under the plan. Such access may be provided through contractual arrangements with specialized providers outside of the network of the plan.

"(2) RULE OF CONSTRUCTION.—Nothing in paragraph (1) shall be construed—

"(A) to require the coverage under a group health plan of particular benefits or services or to prohibit a plan from including providers only to the extent necessary to meet the needs of the plan's participants or beneficiaries or from establishing any measure designed to maintain quality and control costs consistent with the responsibilities of the plan; or

"(B) to override any State licensure or scope-of-practice law.

"(b) TREATMENT PLANS.—

"(1) IN GENERAL.—Nothing in this section shall be construed to prohibit a group health plan (other than a fully insured group health plan) from requir-

ing that specialty care be provided pursuant to a treatment plan so long as the treatment plan is—

"(A) developed by the specialist, in consultation with the case manager or primary care provider, and the participant or beneficiary;

"(B) approved by the plan in a timely manner in accordance with the medical exigencies of the case; and

"(C) in accordance with the applicable quality assurance and utilization review standards of the plan.

"(2) NOTIFICATION.—Nothing in paragraph (1) shall be construed as prohibiting a plan from requiring the specialist to provide the case manager or primary care provider with regular updates on the specialty care provided, as well as all other necessary medical information.

"(c) REFERRALS.—Nothing in this section shall be construed to prohibit a plan from requiring an authorization by the case manager or primary care provider of the participant or beneficiary in order to obtain coverage for specialty services so long as such authorization is for an adequate number of referrals.

"(d) SPECIALTY CARE DEFINED.—For purposes of this subsection, the term 'specialty care' means, with respect to

a condition, care and treatment provided by a health care practitioner, facility, or center (such as a center of excellence) that has adequate expertise (including age-appropriate expertise) through appropriate training and experience.

"SEC. 9826. CONTINUITY OF CARE.

"(a) IN GENERAL.—

"(1) TERMINATION OF PROVIDER.—If a contract between a group health plan (other than a fully insured group health plan) and a health care provider is terminated (as defined in paragraph (2)), or benefits or coverage provided by a health care provider are terminated because of a change in the terms of provider participation in such group health plan, and an individual who is a participant or beneficiary in the plan is undergoing a course of treatment from the provider at the time of such termination, the plan shall—

"(A) notify the individual on a timely basis of such termination;

"(B) provide the individual with an opportunity to notify the plan of a need for transitional care; and

"(C) in the case of termination described in paragraph (2), (3), or (4) of subsection (b), and

subject to subsection (c), permit the individual to continue or be covered with respect to the course of treatment with the provider's consent during a transitional period (as provided under subsection (b)).

"(2) TERMINATED.—In this section, the term 'terminated' includes, with respect to a contract, the expiration or nonrenewal of the contract by the group health plan, but does not include a termination of the contract by the plan for failure to meet applicable quality standards or for fraud.

"(3) CONTRACTS.—For purposes of this section, the term 'contract between a group health plan (other than a fully insured group health plan) and a health care provider' shall include a contract between such a plan and an organized network of providers.

"(b) TRANSITIONAL PERIOD.—

"(1) GENERAL RULE.—Except as provided in paragraph (3), the transitional period under this subsection shall permit the participant or beneficiary to extend the coverage involved for up to 90 days from the date of the notice described in subsection (a)(1)(A) of the provider's termination.

"(2) INSTITUTIONAL CARE.—Subject to paragraph (1), the transitional period under this sub-

section for institutional or inpatient care from a provider shall extend until the discharge or termination of the period of institutionalization and also shall include institutional care provided within a reasonable time of the date of termination of the provider status if the care was scheduled before the date of the announcement of the termination of the provider status under subsection (a)(1)(A) or if the individual on such date was on an established waiting list or otherwise scheduled to have such care.

"(3) PREGNANCY.—Notwithstanding paragraph (1), if—

"(A) a participant or beneficiary has entered the second trimester of pregnancy at the time of a provider's termination of participation; and

"(B) the provider was treating the pregnancy before the date of the termination;

the transitional period under this subsection with respect to provider's treatment of the pregnancy shall extend through the provision of post-partum care directly related to the delivery.

"(4) TERMINAL ILLNESS.—Notwithstanding paragraph (1), if—

"(A) a participant or beneficiary was determined to be terminally ill (as determined under section 1861(dd)(3)(A) of the Social Security Act) prior to a provider's termination of participation; and

"(B) the provider was treating the terminal illness before the date of termination;

the transitional period under this subsection shall be for care directly related to the treatment of the terminal illness and shall extend for the remainder of the individual's life for such care.

"(c) PERMISSIBLE TERMS AND CONDITIONS.—A group health plan (other than a fully insured group health plan) may condition coverage of continued treatment by a provider under subsection (a)(1)(C) upon the provider agreeing to the following terms and conditions:

"(1) The provider agrees to accept reimbursement from the plan and individual involved (with respect to cost-sharing) at the rates applicable prior to the start of the transitional period as payment in full (or at the rates applicable under the replacement plan after the date of the termination of the contract with the group health plan) and not to impose cost-sharing with respect to the individual in an amount that would exceed the cost-sharing that could have been

imposed if the contract referred to in subsection (a)(1) had not been terminated.

"(2) The provider agrees to adhere to the quality assurance standards of the plan responsible for payment under paragraph (1) and to provide to such plan necessary medical information related to the care provided.

"(3) The provider agrees otherwise to adhere to such plan's policies and procedures, including procedures regarding referrals and obtaining prior authorization and providing services pursuant to a treatment plan (if any) approved by the plan.

"(d) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to require the coverage of benefits which would not have been covered if the provider involved remained a participating provider.

"(e) DEFINITION.—In this section, the term 'health care provider' or 'provider' means—

"(1) any individual who is engaged in the delivery of health care services in a State and who is required by State law or regulation to be licensed or certified by the State to engage in the delivery of such services in the State; and

"(2) any entity that is engaged in the delivery of health care services in a State and that, if it is re-

quired by State law or regulation to be licensed or certified by the State to engage in the delivery of such services in the State, is so licensed.

"(f) COMPREHENSIVE STUDY OF COST, QUALITY AND COORDINATION OF COVERAGE FOR PATIENTS AT THE END OF LIFE.—

"(1) STUDY BY THE MEDICARE PAYMENT ADVISORY COMMISSION.—The Medicare Payment Advisory Commission shall conduct a study of the costs and patterns of care for persons with serious and complex conditions and the possibilities of improving upon that care to the degree it is triggered by the current category of terminally ill as such term is used for purposes of section 1861(dd) of the Social Security Act (relating to hospice benefits) or of utilizing care in other payment settings in Medicare.

"(2) AGENCY FOR HEALTH CARE POLICY AND RESEARCH.—The Agency for Health Care Policy and Research shall conduct studies of the possible thresholds for major conditions causing serious and complex illness, their administrative parameters and feasibility, and their impact upon costs and quality.

"(3) HEALTH CARE FINANCING ADMINISTRATION.—The Health Care Financing Administration shall conduct studies of the merits of applying similar

thresholds in Medicare+Choice programs, including adapting risk adjustment methods to account for this category.

"(4) INITIAL REPORT.—

"(A) IN GENERAL.—Not later than 12 months after the date of enactment of this section, the Medicare Payment Advisory Commission and the Agency for Health Care Policy and Research shall each prepare and submit to the Committee on Health, Education, Labor and Pensions of the Senate a report concerning the results of the studies conducted under paragraphs (1) and (2), respectively.

"(B) COPY TO SECRETARY.—Concurrent with the submission of the reports under subparagraph (A), the Medicare Payment Advisory Commission and the Agency for health Care Policy and Research shall transmit a copy of the reports under such subparagraph to the Secretary.

"(5) FINAL REPORT.—

"(A) CONTRACT WITH INSTITUTE OF MEDICINE.—Not later than 1 year after the submission of the reports under paragraph (4), the Secretary of Health and Human Services shall contract with the Institute of Medicine to conduct a

study of the practices and their effects arising from the utilization of the category "serious and complex" illness.

"(B) REPORT.—Not later than 1 year after the date of the execution of the contract referred to in subparagraph (A), the Institute of Medicine shall prepare and submit to the Committee on Health, Education, Labor and Pensions of the Senate a report concerning the study conducted pursuant to such contract.

"(6) FUNDING.—From funds appropriated to the Department of Health and Human Services, the Secretary of Health and Human Services shall make available such funds as the Secretary determines is necessary to carry out this subsection.

"SEC. 9827. PROTECTION OF PATIENT-PROVIDER COMMUNICATIONS.

"(a) IN GENERAL.—Subject to subsection (b), a group health plan (other than a fully insured group health plan and in relation to a participant or beneficiary) shall not prohibit or otherwise restrict a health care professional from advising such a participant or beneficiary who is a patient of the professional about the health status of the participant or beneficiary or medical care or treatment for the condition or disease of the participant or beneficiary, regardless of

whether coverage for such care or treatment are provided under the contract, if the professional is acting within the lawful scope of practice.

"(b) RULE OF CONSTRUCTION.—Nothing in this section shall be construed as requiring a group health plan (other than a fully insured group health plan) to provide specific benefits under the terms of such plan.

"SEC. 9828. PATIENT'S RIGHT TO PRESCRIPTION DRUGS.

"To the extent that a group health plan (other than a fully insured group health plan) provides coverage for benefits with respect to prescription drugs, and limits such coverage to drugs included in a formulary, the plan shall—

"(1) ensure the participation of physicians and pharmacists in developing and reviewing such formulary; and

"(2) in accordance with the applicable quality assurance and utilization review standards of the plan, provide for exceptions from the formulary limitation when a non-formulary alternative is medically necessary and appropriate.

"SEC. 9829. SELF-PAYMENT FOR BEHAVIORAL HEALTH CARE SERVICES.

"(a) IN GENERAL.—A group health plan (other than a fully insured group health plan) may not—

"(1) prohibit or otherwise discourage a participant or beneficiary from self-paying for behavioral health care services once the plan has denied coverage for such services; or

"(2) terminate a health care provider because such provider permits participants or beneficiaries to self-pay for behavioral health care services—

"(A) that are not otherwise covered under the plan; or

"(B) for which the group health plan provides limited coverage, to the extent that the group health plan denies coverage of the services.

"(b) RULE OF CONSTRUCTION.—Nothing in subsection (a)(2)(B) shall be construed as prohibiting a group health plan from terminating a contract with a health care provider for failure to meet applicable quality standards or for fraud.

"SEC. 9830. COVERAGE FOR INDIVIDUALS PARTICIPATING IN APPROVED CANCER CLINICAL TRIALS.

"(a) COVERAGE.—

"(1) IN GENERAL.—If a group health plan (other than a fully insured group health plan) provides coverage to a qualified individual (as defined in subsection (b)), the plan—

"(A) may not deny the individual participation in the clinical trial referred to in subsection (b)(2);

"(B) subject to subsections (b), (c), and (d) may not deny (or limit or impose additional conditions on) the coverage of routine patient costs for items and services furnished in connection with participation in the trial; and

"(C) may not discriminate against the individual on the basis of the participant's or beneficiaries participation in such trial.

"(2) EXCLUSION OF CERTAIN COSTS.—For purposes of paragraph (1)(B), routine patient costs do not include the cost of the tests or measurements conducted primarily for the purpose of the clinical trial involved.

"(3) USE OF IN-NETWORK PROVIDERS.—If one or more participating providers is participating in a clinical trial, nothing in paragraph (1) shall be construed as preventing a plan from requiring that a qualified individual participate in the trial through such a participating provider if the provider will accept the individual as a participant in the trial.

"(b) QUALIFIED INDIVIDUAL DEFINED.—For purposes of subsection (a), the term "qualified individual" means an

individual who is a participant or beneficiary in a group health plan and who meets the following conditions:

"(1)(A) The individual has been diagnosed with cancer for which no standard treatment is effective.

"(B) The individual is eligible to participate in an approved clinical trial according to the trial protocol with respect to treatment of such illness.

"(C) The individual's participation in the trial offers meaningful potential for significant clinical benefit for the individual.

"(2) Either—

"(A) the referring physician is a participating health care professional and has concluded that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1); or

"(B) the participant or beneficiary provides medical and scientific information establishing that the individual's participation in such trial would be appropriate based upon the individual meeting the conditions described in paragraph (1).

"(c) PAYMENT.—

"(1) IN GENERAL.—Under this section a group health plan (other than a fully insured group health plan) shall provide for payment for routine patient costs described in subsection (a)(2) but is not required to pay for costs of items and services that are reasonably expected to be paid for by the sponsors of an approved clinical trial.

"(2) STANDARDS FOR DETERMINING ROUTINE PATIENT COSTS ASSOCIATED WITH CLINICAL TRIAL PARTICIPATION.—

"(A) IN GENERAL.—The Secretary shall establish, on an expedited basis and using a negotiated rulemaking process under subchapter III of chapter 5 of title 5, United States Code, standards relating to the coverage of routine patient costs for individuals participating in clinical trials that group health plans must meet under this section.

"(B) FACTORS.—In establishing routine patient cost standards under subparagraph (A), the Secretary shall consult with interested parties and take into account —

"(i) quality of patient care;

"(ii) routine patient care costs versus costs associated with the conduct of clinical

trials, including unanticipated patient care costs as a result of participation in clinical trials; and

"(iii) previous and on-going studies relating to patient care costs associated with participation in clinical trials.

"(C) PUBLICATION OF NOTICE.—In carrying out the rulemaking process under this paragraph, the Secretary, after consultation with organizations representing cancer patients, health care practitioners, medical researchers, employers, group health plans, manufacturers of drugs, biologics and medical devices, medical economists, hospitals, and other interested parties, shall publish notice provided for under section 564(a) of title 5, United States Code, by not later than 45 days after the date of the enactment of this section.

"(D) TARGET DATE FOR PUBLICATION OF RULE.—As part of the notice under subparagraph (C), and for purposes of this paragraph, the 'target date for publication' (referred to in section 564(a)(5) of such title 5) shall be June 30, 2000.

"(E) ABBREVIATED PERIOD FOR SUBMISSION OF COMMENTS.—In applying section 564(c) of such title 5 under this paragraph, '15 days' shall be substituted for '30 days'.

"(F) APPOINTMENT OF NEGOTIATED RULEMAKING COMMITTEE AND FACILITATOR.—The Secretary shall provide for—

"(i) the appointment of a negotiated rulemaking committee under section 565(a) of such title 5 by not later than 30 days after the end of the comment period provided for under section 564(c) of such title 5 (as shortened under subparagraph (E)), and

"(ii) the nomination of a facilitator under section 566(c) of such title 5 by not later than 10 days after the date of appointment of the committee.

"(G) PRELIMINARY COMMITTEE REPORT.—The negotiated rulemaking committee appointed under subparagraph (F) shall report to the Secretary, by not later than March 29, 2000, regarding the committee's progress on achieving a consensus with regard to the rulemaking proceeding and whether such consensus is likely to

occur before 1 month before the target date for publication of the rule. If the committee reports that the committee has failed to make significant progress towards such consensus or is unlikely to reach such consensus by the target date, the Secretary may terminate such process and provide for the publication of a rule under this paragraph through such other methods as the Secretary may provide.

"(H) FINAL COMMITTEE REPORT.—If the committee is not terminated under subparagraph (G), the rulemaking committee shall submit a report containing a proposed rule by not later than 1 month before the target date of publication.

"(I) FINAL EFFECT.—The Secretary shall publish a rule under this paragraph in the Federal Register by not later than the target date of publication.

"(J) PUBLICATION OF RULE AFTER PUBLIC COMMENT.—The Secretary shall provide for consideration of such comments and republication of such rule by not later than 1 year after the target date of publication.

"(K) EFFECTIVE DATE.—The provisions of this paragraph shall apply to group health plans (other than a fully insured group health plan) for plan years beginning on or after January 1, 2001.

"(3) PAYMENT RATE.—In the case of covered items and services provided by—

"(A) a participating provider, the payment rate shall be at the agreed upon rate, or

"(B) a nonparticipating provider, the payment rate shall be at the rate the plan would normally pay for comparable services under subparagraph (A).

"(d) APPROVED CLINICAL TRIAL DEFINED.—

"(1) IN GENERAL.—In this section, the term 'approved clinical trial' means a cancer clinical research study or cancer clinical investigation approved and funded (which may include funding through in-kind contributions) by one or more of the following:

"(A) The National Institutes of Health.

"(B) A cooperative group or center of the National Institutes of Health.

"(C) Either of the following if the conditions described in paragraph (2) are met:

"(i) The Department of Veterans Affairs.

"(ii) The Department of Defense.

"(2) CONDITIONS FOR DEPARTMENTS.—The conditions described in this paragraph, for a study or investigation conducted by a Department, are that the study or investigation has been reviewed and approved through a system of peer review that the Secretary determines—

"(A) to be comparable to the system of peer review of studies and investigations used by the National Institutes of Health, and

"(B) assures unbiased review of the highest scientific standards by qualified individuals who have no interest in the outcome of the review.

"(e) CONSTRUCTION.—Nothing in this section shall be construed to limit a plan's coverage with respect to clinical trials.

"(f) PLAN SATISFACTION OF CERTAIN REQUIREMENTS; RESPONSIBILITIES OF FIDUCIARIES.—

"(1) IN GENERAL.—For purposes of this section, insofar as a group health plan provides benefits in the form of health insurance coverage through a health insurance issuer, the plan shall be treated as meeting the requirements of this section with respect to such

benefits and not be considered as failing to meet such requirements because of a failure of the issuer to meet such requirements so long as the plan sponsor or its representatives did not cause such failure by the issuer.

"(2) CONSTRUCTION.—Nothing in this section shall be construed to affect or modify the responsibilities of the fiduciaries of a group health plan under part 4 of subtitle B of title I of the Employee Retirement Income Security Act of 1974.

"(g) STUDY AND REPORT.—

"(1) STUDY.—The Secretary shall study the impact on group health plans for covering routine patient care costs for individuals who are entitled to benefits under this section and who are enrolled in an approved cancer clinical trial program.

"(2) REPORT TO CONGRESS.—Not later than January 1, 2005, the Secretary shall submit a report to Congress that contains an assessment of—

"(A) any incremental cost to group health plans resulting from the provisions of this section;

"(B) a projection of expenditures to such plans resulting from this section; and

"(C) any impact on premiums resulting from this section.

"SEC. 9830A. PROHIBITING DISCRIMINATION AGAINST PROVIDERS.

"(a) IN GENERAL.—A group health plan (other than a fully insured group health plan) shall not discriminate with respect to participation or indemnification as to any provider who is acting within the scope of the provider's license or certification under applicable State law, solely on the basis of such license or certification. This subsection shall not be construed as requiring the coverage under a plan of particular benefits or services or to prohibit a plan from including providers only to the extent necessary to meet the needs of the plan's participants and beneficiaries or from establishing any measure designed to maintain quality and control costs consistent with the responsibilities of the plan.

"(b) NO REQUIREMENT FOR ANY WILLING PROVIDER.—Nothing in this section shall be construed as requiring a group health plan that offers network coverage to include for participation every willing provider or health professional who meets the terms and conditions of the plan.

"SEC. 9830B. GENERALLY APPLICABLE PROVISION.

"In the case of a group health plan that provides benefits under 2 or more coverage options, the requirements of

this subchapter shall apply separately with respect to each coverage option.".

(b) DEFINITION.—Section 9832(b) of the Internal Revenue Code of 1986 is amended by adding at the end the following:

"(4) FULLY INSURED GROUP HEALTH PLAN.—The term 'fully insured group health plan' means a group health plan where benefits under the plan are provided pursuant to the terms of an arrangement between a group health plan and a health insurance issuer and are guaranteed by the health insurance issuer under a contract or policy of insurance.".

(c) CONFORMING AMENDMENT.—Chapter 98 of the Internal Revenue Code of 1986 is amended in the table of subchapters in the item relating to subchapter C, by striking "Subchapter C" and inserting "Subchapter D".

SEC. 103. EFFECTIVE DATE AND RELATED RULES.

(a) IN GENERAL.—The amendments made by this subtitle shall apply with respect to plan years beginning on or after January 1 of the second calendar year following the date of the enactment of this Act. The Secretary shall issue all regulations necessary to carry out the amendments made by this section before the effective date thereof.

(b) LIMITATION ON ENFORCEMENT ACTIONS.—No enforcement action shall be taken, pursuant to the amend-

ments made by this subtitle, against a group health plan with respect to a violation of a requirement imposed by such amendments before the date of issuance of regulations issued in connection with such requirement, if the plan has sought to comply in good faith with such requirement.

Subtitle B—Right to Information About Plans and Providers

SEC. 111. INFORMATION ABOUT PLANS.

(a) EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.—

(1) IN GENERAL.—Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1185 et seq.) is amended by adding at the end the following:

"SEC. 714. HEALTH PLAN COMPARATIVE INFORMATION.

"(a) REQUIREMENT.—

"(1) IN GENERAL.—A group health plan, and a health insurance issuer that provides coverage in connection with group health insurance coverage, shall, not later than 12 months after the date of enactment of this section, and at least annually thereafter, provide for the disclosure, in a clear and accurate form to each participant and each beneficiary who does not reside at the same address as the participant, or upon request to an individual eligible for coverage under

the plan, of the information described in subsection (b).

"(2) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prevent a plan or issuer from entering into any agreement under which the issuer agrees to assume responsibility for compliance with the requirements of this section and the plan is released from liability for such compliance.

"(3) PROVISION OF INFORMATION.—Information shall be provided to participants and beneficiaries under this section at the address maintained by the plan or issuer with respect to such participants or beneficiaries.

"(b) REQUIRED INFORMATION.—The informational materials to be distributed under this section shall include for each package option available under a group health plan the following:

"(1) A description of the covered items and services under each such plan and any in- and out-of-network features of each such plan, including a summary description of the specific exclusions from coverage under the plan.

"(2) A description of any cost-sharing, including premiums, deductibles, coinsurance, and copayment amounts, for which the participant or beneficiary will

be responsible, including any annual or lifetime limits on benefits, for each such plan.

"(3) A description of any optional supplemental benefits offered by each such plan and the terms and conditions (including premiums or cost-sharing) for such supplemental coverage.

"(4) A description of any restrictions on payments for services furnished to a participant or beneficiary by a health care professional that is not a participating professional and the liability of the participant or beneficiary for additional payments for these services.

"(5) A description of the service area of each such plan, including the provision of any out-of-area coverage.

"(6) A description of the extent to which participants and beneficiaries may select the primary care provider of their choice, including providers both within the network and outside the network of each such plan (if the plan permits out-of-network services).

"(7) A description of the procedures for advance directives and organ donation decisions if the plan maintains such procedures.

"(8) A description of the requirements and procedures to be used to obtain preauthorization for health services (including telephone numbers and mailing addresses), including referrals for specialty care.

"(9) A description of the definition of medical necessity used in making coverage determinations by each such plan.

"(10) A summary of the rules and methods for appealing coverage decisions and filing grievances (including telephone numbers and mailing addresses), as well as other available remedies.

"(11) A summary description of any provisions for obtaining off-formulary medications if the plan utilizes a defined formulary for providing specific prescription medications.

"(12) A summary of the rules for access to emergency room care. Also, any available educational material regarding proper use of emergency services.

"(13) A description of whether or not coverage is provided for experimental treatments, investigational treatments, or clinical trials and the circumstances under which access to such treatments or trials is made available.

"(14) A description of the specific preventative services covered under the plan if such services are covered.

"(15) A statement regarding—

"(A) the manner in which a participant or beneficiary may access an obstetrician, gynecologist, or pediatrician in accordance with section 723 or 724; and

"(B) the manner in which a participant or beneficiary obtains continuity of care as provided for in section 726.

"(16) A statement that the following information, and instructions on obtaining such information (including telephone numbers and, if available, Internet websites), shall be made available upon request:

"(A) The names, addresses, telephone numbers, and State licensure status of the plan's participating health care professionals and participating health care facilities, and, if available, the education, training, specialty qualifications or certifications of such professionals.

"(B) A summary description of the methods used for compensating participating health care professionals, such as capitation, fee-for-service, salary, or a combination thereof. The require-

ment of this subparagraph shall not be construed as requiring plans to provide information concerning proprietary payment methodology.

"(C) A summary description of the methods used for compensating health care facilities, including per diem, fee-for-service, capitation, bundled payments, or a combination thereof. The requirement of this subparagraph shall not be construed as requiring plans to provide information concerning proprietary payment methodology.

"(D) A summary description of the procedures used for utilization review.

"(E) The list of the specific prescription medications included in the formulary of the plan, if the plan uses a defined formulary.

"(F) A description of the specific exclusions from coverage under the plan.

"(G) Any available information related to the availability of translation or interpretation services for non-English speakers and people with communication disabilities, including the availability of audio tapes or information in Braille.

"(H) Any information that is made public by accrediting organizations in the process of ac-

creditation if the plan is accredited, or any additional quality indicators that the plan makes available.

"(c) MANNER OF DISTRIBUTION.—The information described in this section shall be distributed in an accessible format that is understandable to an average plan participant or beneficiary.

"(d) RULE OF CONSTRUCTION.—Nothing in this section may be construed to prohibit a group health plan, or health insurance issuer in connection with group health insurance coverage, from distributing any other additional information determined by the plan or issuer to be important or necessary in assisting participants and beneficiaries or upon request potential participants and beneficiaries in the selection of a health plan or from providing information under subsection (b)(15) as part of the required information.

"(e) CONFORMING REGULATIONS.—The Secretary shall issue regulations to coordinate the requirements on group health plans and health insurance issuers under this section with the requirements imposed under part 1, to reduce duplication with respect to any information that is required to be provided under any such requirements.

"(f) HEALTH CARE PROFESSIONAL.—In this section, the term 'health care professional' means a physician (as

defined in section 1861(r) of the Social Security Act) or other health care professional if coverage for the professional's services is provided under the health plan involved for the services of the professional. Such term includes a podiatrist, optometrist, chiropractor, psychologist, dentist, physician assistant, physical or occupational therapist and therapy assistant, speech-language pathologist, audiologist, registered or licensed practical nurse (including nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, and certified nurse-midwife), licensed certified social worker, registered respiratory therapist, and certified respiratory therapy technician.".

(2) CONFORMING AMENDMENTS.—

(A) Section 732(a) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191a(a)) is amended by striking "section 711, and inserting "sections 711 and 714".

(B) The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1001) is amended by inserting after the item relating to section 713, the following:

"Sec. 714. Health plan comparative information.".

(b) INTERNAL REVENUE CODE OF 1986.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986 is amended—

(1) in the table of sections, by inserting after the item relating to section 9812 the following new item:

"Sec. 9813. Health plan comparative information.";

and

(2) by inserting after section 9812 the following:

"SEC. 9813. HEALTH PLAN COMPARATIVE INFORMATION.

"(a) REQUIREMENT.—

"(1) IN GENERAL.—A group health plan shall, not later than 12 months after the date of enactment of this section, and at least annually thereafter, provide for the disclosure, in a clear and accurate form to each participant and each beneficiary who does not reside at the same address as the participant, or upon request to an individual eligible for coverage under the plan, of the information described in subsection (b).

"(2) RULES OF CONSTRUCTION.—Nothing in this section shall be construed to prevent a plan from entering into any agreement under which a health insurance issuer agrees to assume responsibility for compliance with the requirements of this section and the plan is released from liability for such compliance.

"(3) PROVISION OF INFORMATION.—Information shall be provided to participants and beneficiaries under this section at the address maintained by the

plan with respect to such participants or beneficiaries.

"(b) REQUIRED INFORMATION.—The informational materials to be distributed under this section shall include for each package option available under a group health plan the following:

"(1) A description of the covered items and services under each such plan and any in- and out-of-network features of each such plan, including a summary description of the specific exclusions from coverage under the plan.

"(2) A description of any cost-sharing, including premiums, deductibles, coinsurance, and copayment amounts, for which the participant or beneficiary will be responsible, including any annual or lifetime limits on benefits, for each such plan.

"(3) A description of any optional supplemental benefits offered by each such plan and the terms and conditions (including premiums or cost-sharing) for such supplemental coverage.

"(4) A description of any restrictions on payments for services furnished to a participant or beneficiary by a health care professional that is not a participating professional and the liability of the

participant or beneficiary for additional payments for these services.

"(5) A description of the service area of each such plan, including the provision of any out-of-area coverage.

"(6) A description of the extent to which participants and beneficiaries may select the primary care provider of their choice, including providers both within the network and outside the network of each such plan (if the plan permits out-of-network services).

"(7) A description of the procedures for advance directives and organ donation decisions if the plan maintains such procedures.

"(8) A description of the requirements and procedures to be used to obtain preauthorization for health services (including telephone numbers and mailing addresses), including referrals for specialty care.

"(9) A description of the definition of medical necessity used in making coverage determinations by each such plan.

"(10) A summary of the rules and methods for appealing coverage decisions and filing grievances

(including telephone numbers and mailing addresses), as well as other available remedies.

"(11) A summary description of any provisions for obtaining off-formulary medications if the plan utilizes a defined formulary for providing specific prescription medications.

"(12) A summary of the rules for access to emergency room care. Also, any available educational material regarding proper use of emergency services.

"(13) A description of whether or not coverage is provided for experimental treatments, investigational treatments, or clinical trials and the circumstances under which access to such treatments or trials is made available.

"(14) A description of the specific preventative services covered under the plan if such services are covered.

"(15) A statement regarding—

"(A) the manner in which a participant or beneficiary may access an obstetrician, gynecologist, or pediatrician in accordance with section 723 or 724; and

"(B) the manner in which a participant or beneficiary obtains continuity of care as provided for in section 726.

"(16) A statement that the following information, and instructions on obtaining such information (including telephone numbers and, if available, Internet websites), shall be made available upon request:

"(A) The names, addresses, telephone numbers, and State licensure status of the plan's participating health care professionals and participating health care facilities, and, if available, the education, training, specialty qualifications or certifications of such professionals.

"(B) A summary description of the methods used for compensating participating health care professionals, such as capitation, fee-for-service, salary, or a combination thereof. The requirement of this subparagraph shall not be construed as requiring plans to provide information concerning proprietary payment methodology.

"(C) A summary description of the methods used for compensating health care facilities, including per diem, fee-for-service, capitation, bundled payments, or a combination thereof. The requirement of this subparagraph shall not be construed as requiring plans to provide information concerning proprietary payment methodology.

"(D) A summary description of the procedures used for utilization review.

"(E) The list of the specific prescription medications included in the formulary of the plan, if the plan uses a defined formulary.

"(F) A description of the specific exclusions from coverage under the plan.

"(G) Any available information related to the availability of translation or interpretation services for non-English speakers and people with communication disabilities, including the availability of audio tapes or information in Braille.

"(H) Any information that is made public by accrediting organizations in the process of accreditation if the plan is accredited, or any additional quality indicators that the plan makes available.

"(c) MANNER OF DISTRIBUTION.—The information described in this section shall be distributed in an accessible format that is understandable to an average plan participant or beneficiary.

"(d) RULE OF CONSTRUCTION.—Nothing in this section may be construed to prohibit a group health plan from distributing any other additional information determined

by the plan to be important or necessary in assisting participants and beneficiaries or upon request potential participants and beneficiaries in the selection of a health plan or from providing information under subsection (b)(15) as part of the required information.

"(e) HEALTH CARE PROFESSIONAL.—In this section, the term 'health care professional' means a physician (as defined in section 1861(r) of the Social Security Act) or other health care professional if coverage for the professional's services is provided under the health plan involved for the services of the professional. Such term includes a podiatrist, optometrist, chiropractor, psychologist, dentist, physician assistant, physical or occupational therapist and therapy assistant, speech-language pathologist, audiologist, registered or licensed practical nurse (including nurse practitioner, clinical nurse specialist, certified registered nurse anesthetist, and certified nurse-midwife), licensed certified social worker, registered respiratory therapist, and certified respiratory therapy technician.".

SEC. 112. INFORMATION ABOUT PROVIDERS.

(a) STUDY.—The Secretary of Health and Human Services shall enter into a contract with the Institute of Medicine for the conduct of a study, and the submission to the Secretary of a report, that includes—

(1) an analysis of information concerning health care professionals that is currently available to patients, consumers, States, and professional societies, nationally and on a State-by-State basis, including patient preferences with respect to information about such professionals and their competencies;

(2) an evaluation of the legal and other barriers to the sharing of information concerning health care professionals; and

(3) recommendations for the disclosure of information on health care professionals, including the competencies and professional qualifications of such practitioners, to better facilitate patient choice, quality improvement, and market competition.

(b) REPORT.—Not later than 18 months after the date of enactment of this Act, the Secretary of Health and Human Services shall forward to the appropriate committees of Congress a copy of the report and study conducted under subsection (a).

Subtitle C—Right to Hold Health Plans Accountable

SEC. 121. AMENDMENT TO EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.

(a) IN GENERAL.—Section 503 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1133) is amended to read as follows:

"SEC. 503. CLAIMS PROCEDURE, COVERAGE DETERMINATION, GRIEVANCES AND APPEALS.

"(a) CLAIMS PROCEDURE.—In accordance with regulations of the Secretary, every employee benefit plan shall—

"(1) provide adequate notice in writing to any participant or beneficiary whose claim for benefits under the plan has been denied, setting forth the specific reasons for such denial, written in a manner calculated to be understood by the participant; and

"(2) afford a reasonable opportunity to any participant whose claim for benefits has been denied for a full and fair review by the appropriate named fiduciary of the decision denying the claim.

"(b) COVERAGE DETERMINATIONS UNDER GROUP HEALTH PLANS.—

"(1) PROCEDURES.—

"(A) IN GENERAL.—A group health plan or health insurance issuer conducting utilization re-

view shall ensure that procedures are in place for—

"(i) making determinations regarding whether a participant or beneficiary is eligible to receive a payment or coverage for health services under the plan or coverage involved and any cost-sharing amount that the participant or beneficiary is required to pay with respect to such service;

"(ii) notifying a covered participant or beneficiary (or the authorized representative of such participant or beneficiary) and the treating health care professionals involved regarding determinations made under the plan or issuer and any additional payments that the participant or beneficiary may be required to make with respect to such service; and

"(iii) responding to requests, either written or oral, for coverage determinations or for internal appeals from a participant or beneficiary (or the authorized representative of such participant or beneficiary) or the treating health care professional with

the consent of the participant or beneficiary.

"(B) ORAL REQUESTS.—With respect to an oral request described in subparagraph (A)(iii), a group health plan or health insurance issuer may require that the requesting individual provide written evidence of such request.

"(2) TIMELINE FOR MAKING DETERMINATIONS.—

"(A) ROUTINE DETERMINATION.—A group health plan or a health insurance issuer shall maintain procedures to ensure that prior authorization determinations concerning the provision of non-emergency items or services are made within 30 days from the date on which the request for a determination is submitted, except that such period may be extended where certain circumstances exist that are determined by the Secretary to be beyond control of the plan or issuer.

"(B) EXPEDITED DETERMINATION.—

"(i) IN GENERAL.—A prior authorization determination under this subsection shall be made within 72 hours, in accordance with the medical exigencies of the case,

after a request is received by the plan or issuer under clause (ii) or (iii).

"(ii) REQUEST BY PARTICIPANT OR BENEFICIARY.—A plan or issuer shall maintain procedures for expediting a prior authorization determination under this subsection upon the request of a participant or beneficiary if, based on such a request, the plan or issuer determines that the normal time for making such a determination could seriously jeopardize the life or health of the participant or beneficiary.

"(iii) DOCUMENTATION BY HEALTH CARE PROFESSIONAL.—A plan or issuer shall maintain procedures for expediting a prior authorization determination under this subsection if the request involved indicates that the treating health care professional has reasonably documented, based on the medical exigencies, that a determination under the procedures described in subparagraph (A) could seriously jeopardize the life or health of the participant or beneficiary.

"(C) CONCURRENT DETERMINATIONS.—A plan or issuer shall maintain procedures to cer-

tify or deny coverage of an extended stay or additional services.

"(D) RETROSPECTIVE DETERMINATION.—A plan or issuer shall maintain procedures to ensure that, with respect to the retrospective review of a determination made under paragraph (1), the determination shall be made within 30 working days of the date on which the plan or issuer receives necessary information.

"(3) NOTICE OF DETERMINATIONS.—

"(A) ROUTINE DETERMINATION.—With respect to a coverage determination of a plan or issuer under paragraph (2)(A), the plan or issuer shall issue notice of such determination to the participant or beneficiary (or the authorized representative of the participant or beneficiary) and, consistent with the medical exigencies of the case, to the treating health care professional involved not later than 2 working days after the date on which the determination is made.

"(B) EXPEDITED DETERMINATION.—With respect to a coverage determination of a plan or issuer under paragraph (2)(B), the plan or issuer shall issue notice of such determination to the participant or beneficiary (or the authorized

representative of the participant or beneficiary), and consistent with the medical exigencies of the case, to the treating health care professional involved within the 72 hour period described in paragraph (2)(B).

"(C) CONCURRENT REVIEWS.—With respect to the determination under a plan or issuer under paragraph (2)(C) to certify or deny coverage of an extended stay or additional services, the plan or issuer shall issue notice of such determination to the treating health care professional and to the participant or beneficiary involved (or the authorized representative of the participant or beneficiary) within 1 working day of the determination.

"(D) RETROSPECTIVE REVIEWS.—With respect to the retrospective review under a plan or issuer of a determination made under paragraph (2)(D), the plan or issuer shall issue written notice of an approval or disapproval of a determination under this subparagraph to the participant or beneficiary (or the authorized representative of the participant or beneficiary) and health care provider involved within 5 working

days of the date on which such determination is made.

"(E) REQUIREMENTS OF NOTICE OF ADVERSE COVERAGE DETERMINATIONS.—A written notice of an adverse coverage determination under this subsection, or of an expedited adverse coverage determination under paragraph (2)(B), shall be provided to the participant or beneficiary (or the authorized representative of the participant or beneficiary) and treating health care professional (if any) involved and shall include—

"(i) the reasons for the determination (including the clinical or scientific-evidence based rationale used in making the determination) written in a manner to be understandable to the average participant or beneficiary;

"(ii) the procedures for obtaining additional information concerning the determination; and

"(iii) notification of the right to appeal the determination and instructions on how to initiate an appeal in accordance with subsection (d).

"(c) GRIEVANCES.—A group health plan or a health insurance issuer shall have written procedures for addressing grievances between the plan or issuer offering health insurance coverage in connection with a group health plan and a participant or beneficiary. Determinations under such procedures shall be non-appealable.

"(d) INTERNAL APPEAL OF COVERAGE DETERMINATIONS.—

"(1) RIGHT TO APPEAL.—

"(A) IN GENERAL.—A participant or beneficiary (or the authorized representative of the participant or beneficiary) or the treating health care professional with the consent of the participant or beneficiary (or the authorized representative of the participant or beneficiary), may appeal any adverse coverage determination under subsection (b) under the procedures described in this subsection.

"(B) TIME FOR APPEAL.—A plan or issuer shall ensure that a participant or beneficiary has a period of not less than 180 days beginning on the date of an adverse coverage determination under subsection (b) in which to appeal such determination under this subsection.

"(C) FAILURE TO ACT.—The failure of a plan or issuer to issue a determination under subsection (b) within the applicable timeline established for such a determination under such subsection shall be treated as an adverse coverage determination for purposes of proceeding to internal review under this subsection.

"(2) RECORDS.—A group health plan and a health insurance issuer shall maintain written records, for at least 6 years, with respect to any appeal under this subsection for purposes of internal quality assurance and improvement. Nothing in the preceding sentence shall be construed as preventing a plan and issuer from entering into an agreement under which the issuer agrees to assume responsibility for compliance with the requirements of this section and the plan is released from liability for such compliance.

"(3) ROUTINE DETERMINATIONS.—A group health plan or a health insurance issuer shall complete the consideration of an appeal of an adverse routine determination under this subsection not later than 30 working days after the date on which a request for such appeal is received.

"(4) EXPEDITED DETERMINATION.—

"(A) IN GENERAL.—An expedited determination with respect to an appeal under this subsection shall be made in accordance with the medical exigencies of the case, but in no case more than 72 hours after the request for such appeal is received by the plan or issuer under subparagraph (B) or (C).

"(B) REQUEST BY PARTICIPANT OR BENEFICIARY.—A plan or issuer shall maintain procedures for expediting a prior authorization determination under this subsection upon the request of a participant or beneficiary if, based on such a request, the plan or issuer determines that the normal time for making such a determination could seriously jeopardize the life or health of the participant or beneficiary.

"(C) DOCUMENTATION BY HEALTH CARE PROFESSIONAL.—A plan or issuer shall maintain procedures for expediting a prior authorization determination under this subsection if the request involved indicates that the treating health care professional has reasonably documented, based on the medical exigencies of the case that a determination under the procedures described in paragraph (2) could seriously jeop-

ardize the life or health of the participant or beneficiary.

"(5) CONDUCT OF REVIEW.—A review of an adverse coverage determination under this subsection shall be conducted by an individual with appropriate expertise who was not directly involved in the initial determination.

"(6) LACK OF MEDICAL NECESSITY.—A review of an appeal under this subsection relating to a determination to deny coverage based on a lack of medical necessity and appropriateness, or based on an experimental or investigational treatment, shall be made only by a physician with appropriate expertise, including age-appropriate expertise, who was not involved in the initial determination.

"(7) NOTICE.—

"(A) IN GENERAL.—Written notice of a determination made under an internal review process shall be issued to the participant or beneficiary (or the authorized representative of the participant or beneficiary) and the treating health care professional not later than 2 working days after the completion of the review (or within the 72-hour period referred to in paragraph (4) if applicable).

"(B) ADVERSE COVERAGE DETERMINATIONS.—With respect to an adverse coverage determination made under this subsection, the notice described in subparagraph (A) shall include—

"(i) the reasons for the determination (including the clinical or scientific-evidence based rationale used in making the determination) written in a manner to be understandable to the average participant or beneficiary;

"(ii) the procedures for obtaining additional information concerning the determination; and

"(iii) notification of the right to an independent external review under subsection (e) and instructions on how to initiate such a review.

"(e) INDEPENDENT EXTERNAL REVIEW.—

"(1) ACCESS TO REVIEW.—

"(A) IN GENERAL.—A group health plan or a health insurance issuer offering health insurance coverage in connection with a group health plan shall have written procedures to permit a participant or beneficiary (or the authorized rep-

resentative of the participant or beneficiary) access to an independent external review with respect to an adverse coverage determination concerning a particular item or service (including a circumstance treated as an adverse coverage determination under subparagraph (B)) where—

"(i) the particular item or service involved—

"(I)(aa) would be a covered benefit, when medically necessary and appropriate under the terms and conditions of the plan, and the item or service has been determined not to be medically necessary and appropriate under the internal appeals process required under subsection (d) or there has been a failure to issue a coverage determination as described in subparagraph (B); and

"(bb)(AA) the amount of such item or service involved exceeds a significant financial threshold; or

"(BB) there is a significant risk of placing the life or health of the participant or beneficiary in jeopardy; or

"(II) would be a covered benefit, when not considered experimental or investigational under the terms and conditions of the plan, and the item or service has been determined to be experimental or investigational under the internal appeals process required under subsection (d) or there has been a failure to issue a coverage determination as described in subparagraph (B); and

"(ii) the participant or beneficiary has completed the internal appeals process under subsection (d) with respect to such determination.

"(B) FAILURE TO ACT.—The failure of a plan or issuer to issue a coverage determination under subsection (d)(6) within the applicable timeline established for such a determination under such subsection shall be treated as an adverse coverage determination for purposes of proceeding to independent external review under this subsection.

"(2) INITIATION OF THE INDEPENDENT EXTERNAL REVIEW PROCESS.—

"(A) FILING OF REQUEST.—A participant or beneficiary (or the authorized representative of the participant or beneficiary) who desires to have an independent external review conducted under this subsection shall file a written request for such a review with the plan or issuer involved not later than 30 working days after the receipt of a final denial of a claim under subsection (d). Any such request shall include the consent of the participant or beneficiary (or the authorized representative of the participant or beneficiary) for the release of medical information and records to independent external reviewers regarding the participant or beneficiary.

"(B) TIMEFRAME FOR SELECTION OF APPEALS ENTITY.—Not later than 5 working days after the receipt of a request under subparagraph (A), or earlier in accordance with the medical exigencies of the case, the plan or issuer involved shall—

"(i) select an external appeals entity under paragraph (3)(A) that shall be responsible for designating an independent external reviewer under paragraph (3)(B); and

"(ii) provide notice of such selection to the participant or beneficiary (which shall include the name and address of the entity).

"(C) PROVISION OF INFORMATION.—Not later than 5 working days after the plan or issuer provides the notice required under subparagraph (B)(ii), or earlier in accordance with the medical exigencies of the case, the plan, issuer, participant, beneficiary or physician (of the participant or beneficiary) involved shall forward necessary information (including, only in the case of a plan or issuer, medical records, any relevant review criteria, the clinical rationale consistent with the terms and conditions of the contract between the plan or issuer and the participant or beneficiary for the coverage denial, and evidence of the coverage of the participant or beneficiary) to the qualified external appeals entity designated under paragraph (3)(A).

"(D) FOLLOW-UP WRITTEN NOTIFICATION.—The plan or issuer involved shall send a follow-up written notification, in a timely manner, to the participant or beneficiary (or the authorized representative of the participant or beneficiary) and the plan administrator, indicating

that an independent external review has been initiated.

"(3) CONDUCT OF INDEPENDENT EXTERNAL REVIEW.—

"(A) DESIGNATION OF EXTERNAL APPEALS ENTITY BY PLAN OR ISSUER.—

"(i) IN GENERAL.—A plan or issuer that receives a request for an independent external review under paragraph (2)(A) shall designate a qualified entity described in clause (ii), in a manner designed to ensure that the entity so designated will make a decision in an unbiased manner, to serve as the external appeals entity.

"(ii) QUALIFIED ENTITIES.—A qualified entity shall be—

"(I) an independent external review entity licensed or credentialed by a State;

"(II) a State agency established for the purpose of conducting independent external reviews;

"(III) any entity under contract with the Federal Government to pro-

vide independent external review services;

"(IV) any entity accredited as an independent external review entity by an accrediting body recognized by the Secretary for such purpose; or

"(V) any other entity meeting criteria established by the Secretary for purposes of this subparagraph.

"(B) DESIGNATION OF INDEPENDENT EXTERNAL REVIEWER BY EXTERNAL APPEALS ENTITY.—The external appeals entity designated under subparagraph (A) shall, not later than 30 days after the date on which such entity is designated under subparagraph (A), or earlier in accordance with the medical exigencies of the case, designate one or more individuals to serve as independent external reviewers with respect to a request received under paragraph (2)(A). Such reviewers shall be independent medical experts who shall—

"(i) be appropriately credentialed or licensed in any State to deliver health care services;

"(ii) not have any material, professional, familial, or financial affiliation with the case under review, the participant or beneficiary involved, the treating health care professional, the institution where the treatment would take place, or the manufacturer of any drug, device, procedure, or other therapy proposed for the participant or beneficiary whose treatment is under review;

"(iii) have expertise (including age-appropriate expertise) in the diagnosis or treatment under review and be a physician of the same specialty, when reasonably available, as the physician treating the participant or beneficiary or recommending or prescribing the treatment in question;

"(iv) receive only reasonable and customary compensation from the group health plan or health insurance issuer in connection with the independent external review that is not contingent on the decision rendered by the reviewer; and

"(v) not be held liable for decisions regarding medical determinations (but may

be held liable for actions that are arbitrary and capricious).

"(4) STANDARD OF REVIEW.—

"(A) IN GENERAL.—An independent external reviewer shall—

"(i) make an independent determination based on the valid, relevant, scientific and clinical evidence to determine the medical necessity, appropriateness, experimental or investigational nature of the proposed treatment; and

"(ii) take into consideration appropriate and available information, including any evidence-based decision making or clinical practice guidelines used by the group health plan or health insurance issuer; timely evidence or information submitted by the plan, issuer, patient or patient's physician; the patient's medical record; expert consensus including both generally accepted medical practice and recognized best practice; medical literature as defined in section 556(5) of the Federal Food, Drug, and Cosmetic Act; the following standard reference compendia: The American Hospital For-

mulary Service-Drug Information, the American Dental Association Accepted Dental Therapeutics, and the United States Pharmacopoeia-Drug Information; and findings, studies, or research conducted by or under the auspices of Federal Government agencies and nationally recognized Federal research institutes including the Agency for Healthcare Research and Quality, National Institutes of Health, National Academy of Sciences, Health Care Financing Administration, and any national board recognized by the National Institutes of Health for the purposes of evaluating the medical value of health services.

"(B) NOTICE.—The plan or issuer involved shall ensure that the participant or beneficiary receives notice, within 30 days after the determination of the independent medical expert, regarding the actions of the plan or issuer with respect to the determination of such expert under the independent external review.

"(5) TIMEFRAME FOR REVIEW.—

"(A) IN GENERAL.—The independent external reviewer shall complete a review of an ad-

verse coverage determination in accordance with the medical exigencies of the case.

"(B) EXPEDITED REVIEW.—Notwithstanding subparagraph (A), a review described in such subparagraph shall be completed not later than 72 hours after the later of—

"(i) the date on which such reviewer is designated; or

"(ii) the date on which all information necessary to completing such review is received;

if the completion of such review in a period of time in excess of 72 hours would seriously jeopardize the life or health of the participant or beneficiary.

"(C) LIMITATION.—Notwithstanding subparagraph (A), and except as provided in subparagraph (B), a review described in subparagraph (A) shall be completed not later than 30 working days after the later of—

"(i) the date on which such reviewer is designated; or

"(ii) the date on which all information necessary to completing such review is received.

"(6) BINDING DETERMINATION AND ACCESS TO CARE.—

"(A) IN GENERAL.—The determination of an independent external reviewer under this subsection shall be binding upon the plan or issuer if the provisions of this subsection or the procedures implemented under such provisions were complied with by the independent external reviewer.

"(B) TIMETABLE FOR COMMENCEMENT OF CARE.—Where an independent external reviewer determines that the participant or beneficiary is entitled to coverage of the items or services that were the subject of the review, the reviewer shall establish a timeframe, in accordance with the medical exigencies of the case, during which the plan or issuer shall comply with the decision of the reviewer with respect to the coverage of such items or services under the terms and conditions of the plan.

"(C) FAILURE TO COMPLY.—If a plan or issuer fails to comply with the timeframe established under subparagraph (B) with respect to a participant or beneficiary, where such failure to comply is caused by the plan or issuer, the par-

ticipant or beneficiary may obtain the items or services involved (in a manner consistent with the determination of the independent external reviewer) from any provider regardless of whether such provider is a participating provider under the plan or coverage.

"(D) REIMBURSEMENT.—

"(i) IN GENERAL.—Where a participant or beneficiary obtains items or services in accordance with subparagraph (C), the plan or issuer involved shall provide for reimbursement of the costs of such items of services. Such reimbursement shall be made to the treating provider or to the participant or beneficiary (in the case of a participant or beneficiary who pays for the costs of such items or services).

"(ii) AMOUNT.—The plan or issuer shall fully reimburse a provider, participant or beneficiary under clause (i) for the total costs of the items or services provided (regardless of any plan limitations that may apply to the coverage of such items of services) so long as—

"(I) the items or services would have been covered under the terms of the plan or coverage if provided by the plan or issuer; and

"(II) the items or services were provided in a manner consistent with the determination of the independent external reviewer.

"(E) FAILURE TO REIMBURSE.—Where a plan or issuer fails to provide reimbursement to a provider, participant or beneficiary in accordance with this paragraph, the provider, participant or beneficiary may commence a civil action (or utilize other remedies available under law) to recover only the amount of any such reimbursement that is unpaid and any necessary legal costs or expenses (including attorneys' fees) incurred in recovering such reimbursement.

"(7) STUDY.—Not later than 2 years after the date of enactment of this section, the General Accounting Office shall conduct a study of a statistically appropriate sample of completed independent external reviews. Such study shall include an assessment of the process involved during an independent external review and the basis of decisionmaking by the inde-

pendent external reviewer. The results of such study shall be submitted to the appropriate committees of Congress.

"(8) EFFECT ON CERTAIN PROVISIONS.—Nothing in this section shall be construed as affecting or modifying section 514 of this Act with respect to a group health plan.

"(f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to prohibit a plan administrator or plan fiduciary or health plan medical director from requesting an independent external review by an independent external reviewer without first completing the internal review process.

"(g) DEFINITIONS.—In this section:

"(1) ADVERSE COVERAGE DETERMINATION.—The term 'adverse coverage determination' means a coverage determination under the plan which results in a denial of coverage or reimbursement.

"(2) COVERAGE DETERMINATION.—The term 'coverage determination' means with respect to items and services for which coverage may be provided under a health plan, a determination of whether or not such items and services are covered or reimbursable under the coverage and terms of the contract.

"(3) GRIEVANCE.—The term 'grievance' means any complaint made by a participant or beneficiary that does not involve a coverage determination.

"(4) GROUP HEALTH PLAN.—The term 'group health plan' shall have the meaning given such term in section 733(a). In applying this paragraph, excepted benefits described in section 733(c) shall not be treated as benefits consisting of medical care.

"(5) HEALTH INSURANCE COVERAGE.—The term 'health insurance coverage' has the meaning given such term in section 733(b)(1). In applying this paragraph, excepted benefits described in section 733(c) shall not be treated as benefits consisting of medical care.

"(6) HEALTH INSURANCE ISSUER.—The term 'health insurance issuer' has the meaning given such term in section 733(b)(2).

"(7) PRIOR AUTHORIZATION DETERMINATION.—The term 'prior authorization determination' means a coverage determination prior to the provision of the items and services as a condition of coverage of the items and services under the coverage.

"(8) TREATING HEALTH CARE PROFESSIONAL.—The term 'treating health care professional' with respect to a group health plan, health insurance issuer

or provider sponsored organization means a physician (medical doctor or doctor of osteopathy) or other health care practitioner who is acting within the scope of his or her State licensure or certification for the delivery of health care services and who is primarily responsible for delivering those services to the participant or beneficiary.

"(9) UTILIZATION REVIEW.—The term 'utilization review' with respect to a group health plan or health insurance coverage means a set of formal techniques designed to monitor the use of, or evaluate the clinical necessity, appropriateness, efficacy, or efficiency of, health care services, procedures, or settings. Techniques may include ambulatory review, prospective review, second opinion, certification, concurrent review, case management, discharge planning or retrospective review.".

(b) ENFORCEMENT.—Section 502(c) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1132(c)) is amended by adding at the end the following:

"(8) The Secretary may assess a civil penalty against any plan of up to $10,000 for the plan's failure or refusal to comply with any timeline applicable under section 503(e) or any determination under such section, except that in any case in which treatment was not commenced by the

plan in accordance with the determination of an independent external reviewer, the Secretary shall assess a civil penalty of $10,000 against the plan and the plan shall pay such penalty to the participant or beneficiary involved.".

(c) CONFORMING AMENDMENT.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 is amended by striking the item relating to section 503 and inserting the following new item:

"Sec. 503. Claims procedures, coverage determination, grievances and appeals.".

(d) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to plan years beginning on or after 1 year after the date of enactment of this Act. The Secretary shall issue all regulations necessary to carry out the amendments made by this section before the effective date thereof.

TITLE II—WOMEN'S HEALTH AND CANCER RIGHTS

SEC. 201. WOMEN'S HEALTH AND CANCER RIGHTS.

(a) SHORT TITLE.—This section may be cited as the "Women's Health and Cancer Rights Act of 1999".

(b) FINDINGS.—Congress finds that—

(1) the offering and operation of health plans affect commerce among the States;

(2) health care providers located in a State serve patients who reside in the State and patients who reside in other States; and

(3) in order to provide for uniform treatment of health care providers and patients among the States, it is necessary to cover health plans operating in 1 State as well as health plans operating among the several States.

(c) AMENDMENTS TO ERISA.—

(1) IN GENERAL.—Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974, as amended by section 111(a), is further amended by adding at the end the following:

"SEC. 715. REQUIRED COVERAGE FOR MINIMUM HOSPITAL STAY FOR MASTECTOMIES AND LYMPH NODE DISSECTIONS FOR THE TREATMENT OF BREAST CANCER AND COVERAGE FOR SECONDARY CONSULTATIONS.

"(a) INPATIENT CARE.—

"(1) IN GENERAL.—A group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan, that provides medical and surgical benefits shall ensure that inpatient coverage with respect to the treatment of breast cancer is provided for a period of time as is determined by the attending physician, in consulta-

tion with the patient, to be medically necessary and appropriate following—

"(A) a mastectomy;

"(B) a lumpectomy; or

"(C) a lymph node dissection for the treatment of breast cancer.

"(2) EXCEPTION.—Nothing in this section shall be construed as requiring the provision of inpatient coverage if the attending physician and patient determine that a shorter period of hospital stay is medically appropriate.

"(b) PROHIBITION ON CERTAIN MODIFICATIONS.—In implementing the requirements of this section, a group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan, may not modify the terms and conditions of coverage based on the determination by a participant or beneficiary to request less than the minimum coverage required under subsection (a).

"(c) NOTICE.—A group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan shall provide notice to each participant and beneficiary under such plan regarding the coverage required by this section in accordance with regulations promulgated by the Secretary. Such notice shall

be in writing and prominently positioned in any literature or correspondence made available or distributed by the plan or issuer and shall be transmitted—

"(1) in the next mailing made by the plan or issuer to the participant or beneficiary;

"(2) as part of any yearly informational packet sent to the participant or beneficiary; or

"(3) not later than January 1, 2000;

whichever is earlier.

"(d) SECONDARY CONSULTATIONS.—

"(1) IN GENERAL.—A group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan, that provides coverage with respect to medical and surgical services provided in relation to the diagnosis and treatment of cancer shall ensure that full coverage is provided for secondary consultations by specialists in the appropriate medical fields (including pathology, radiology, and oncology) to confirm or refute such diagnosis. Such plan or issuer shall ensure that full coverage is provided for such secondary consultation whether such consultation is based on a positive or negative initial diagnosis. In any case in which the attending physician certifies in writing that services necessary for such a secondary consultation are

not sufficiently available from specialists operating under the plan with respect to whose services coverage is otherwise provided under such plan or by such issuer, such plan or issuer shall ensure that coverage is provided with respect to the services necessary for the secondary consultation with any other specialist selected by the attending physician for such purpose at no additional cost to the individual beyond that which the individual would have paid if the specialist was participating in the network of the plan.

"(2) EXCEPTION.—Nothing in paragraph (1) shall be construed as requiring the provision of secondary consultations where the patient determines not to seek such a consultation.

"(e) PROHIBITION ON PENALTIES OR INCENTIVES.—A group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan, may not—

"(1) penalize or otherwise reduce or limit the reimbursement of a provider or specialist because the provider or specialist provided care to a participant or beneficiary in accordance with this section;

"(2) provide financial or other incentives to a physician or specialist to induce the physician or specialist to keep the length of inpatient stays of patients

following a mastectomy, lumpectomy, or a lymph node dissection for the treatment of breast cancer below certain limits or to limit referrals for secondary consultations; or

"(3) provide financial or other incentives to a physician or specialist to induce the physician or specialist to refrain from referring a participant or beneficiary for a secondary consultation that would otherwise be covered by the plan or coverage involved under subsection (d).".

(2) CLERICAL AMENDMENT.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974 is amended by inserting after the item relating to section 714 the following new item:

"Sec. 715. Required coverage for minimum hospital stay for mastectomies and lymph node dissections for the treatment of breast cancer and coverage for secondary consultations.".

(d) AMENDMENTS TO PHSA RELATING TO THE GROUP MARKET.—Subpart 2 of part A of title XXVII of the Public Health Service Act (42 U.S.C. 300gg-4 et seq.) is amended by adding at the end the following new section:

"SEC. 2707. REQUIRED COVERAGE FOR MINIMUM HOSPITAL STAY FOR MASTECTOMIES AND LYMPH NODE DISSECTIONS FOR THE TREATMENT OF BREAST CANCER AND COVERAGE FOR SECONDARY CONSULTATIONS.

"(a) INPATIENT CARE.—

"(1) IN GENERAL.—A group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan, that provides medical and surgical benefits shall ensure that inpatient coverage with respect to the treatment of breast cancer is provided for a period of time as is determined by the attending physician, in consultation with the patient, to be medically necessary and appropriate following—

"(A) a mastectomy;

"(B) a lumpectomy; or

"(C) a lymph node dissection for the treatment of breast cancer.

"(2) EXCEPTION.—Nothing in this section shall be construed as requiring the provision of inpatient coverage if the attending physician and patient determine that a shorter period of hospital stay is medically appropriate.

"(b) PROHIBITION ON CERTAIN MODIFICATIONS.—In implementing the requirements of this section, a group

health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan, may not modify the terms and conditions of coverage based on the determination by a participant or beneficiary to request less than the minimum coverage required under subsection (a).

"(c) NOTICE.—A group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan shall provide notice to each participant and beneficiary under such plan regarding the coverage required by this section in accordance with regulations promulgated by the Secretary. Such notice shall be in writing and prominently positioned in any literature or correspondence made available or distributed by the plan or issuer and shall be transmitted—

"(1) in the next mailing made by the plan or issuer to the participant or beneficiary;

"(2) as part of any yearly informational packet sent to the participant or beneficiary; or

"(3) not later than January 1, 2000;

whichever is earlier.

"(d) SECONDARY CONSULTATIONS.—

"(1) IN GENERAL.—A group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan that

provides coverage with respect to medical and surgical services provided in relation to the diagnosis and treatment of cancer shall ensure that full coverage is provided for secondary consultations by specialists in the appropriate medical fields (including pathology, radiology, and oncology) to confirm or refute such diagnosis. Such plan or issuer shall ensure that full coverage is provided for such secondary consultation whether such consultation is based on a positive or negative initial diagnosis. In any case in which the attending physician certifies in writing that services necessary for such a secondary consultation are not sufficiently available from specialists operating under the plan with respect to whose services coverage is otherwise provided under such plan or by such issuer, such plan or issuer shall ensure that coverage is provided with respect to the services necessary for the secondary consultation with any other specialist selected by the attending physician for such purpose at no additional cost to the individual beyond that which the individual would have paid if the specialist was participating in the network of the plan.

"(2) EXCEPTION.—Nothing in paragraph (1) shall be construed as requiring the provision of sec-

ondary consultations where the patient determines not to seek such a consultation.

"(e) PROHIBITION ON PENALTIES OR INCENTIVES.—A group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan, may not—

"(1) penalize or otherwise reduce or limit the reimbursement of a provider or specialist because the provider or specialist provided care to a participant or beneficiary in accordance with this section;

"(2) provide financial or other incentives to a physician or specialist to induce the physician or specialist to keep the length of inpatient stays of patients following a mastectomy, lumpectomy, or a lymph node dissection for the treatment of breast cancer below certain limits or to limit referrals for secondary consultations; or

"(3) provide financial or other incentives to a physician or specialist to induce the physician or specialist to refrain from referring a participant or beneficiary for a secondary consultation that would otherwise be covered by the plan or coverage involved under subsection (d).".

(e) AMENDMENTS TO PHSA RELATING TO THE INDIVIDUAL MARKET.—The first subpart 3 of part B of title

XXVII of the Public Health Service Act (42 U.S.C. 300gg–51 et seq.) (relating to other requirements) (42 U.S.C. 300gg-51 et seq.) is amended—

(1) by redesignating such subpart as subpart 2; and

(2) by adding at the end the following:

"SEC. 2753. REQUIRED COVERAGE FOR MINIMUM HOSPITAL STAY FOR MASTECTOMIES AND LYMPH NODE DISSECTIONS FOR THE TREATMENT OF BREAST CANCER AND SECONDARY CONSULTATIONS.

"The provisions of section 2707 shall apply to health insurance coverage offered by a health insurance issuer in the individual market in the same manner as they apply to health insurance coverage offered by a health insurance issuer in connection with a group health plan in the small or large group market.".

(f) AMENDMENTS TO THE IRC.—

(1) IN GENERAL.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986, as amended by section 111(b), is further amended by inserting after section 9813 the following:

"SEC. 9814. REQUIRED COVERAGE FOR MINIMUM HOSPITAL STAY FOR MASTECTOMIES AND LYMPH NODE DISSECTIONS FOR THE TREATMENT OF BREAST CANCER AND COVERAGE FOR SECONDARY CONSULTATIONS.

"(a) INPATIENT CARE.—

"(1) IN GENERAL.—A group health plan that provides medical and surgical benefits shall ensure that inpatient coverage with respect to the treatment of breast cancer is provided for a period of time as is determined by the attending physician, in consultation with the patient, to be medically necessary and appropriate following—

"(A) a mastectomy;

"(B) a lumpectomy; or

"(C) a lymph node dissection for the treatment of breast cancer.

"(2) EXCEPTION.—Nothing in this section shall be construed as requiring the provision of inpatient coverage if the attending physician and patient determine that a shorter period of hospital stay is medically appropriate.

"(b) PROHIBITION ON CERTAIN MODIFICATIONS.—In implementing the requirements of this section, a group health plan may not modify the terms and conditions of coverage based on the determination by a participant or

beneficiary to request less than the minimum coverage required under subsection (a).

"(c) NOTICE.—A group health plan shall provide notice to each participant and beneficiary under such plan regarding the coverage required by this section in accordance with regulations promulgated by the Secretary. Such notice shall be in writing and prominently positioned in any literature or correspondence made available or distributed by the plan and shall be transmitted—

"(1) in the next mailing made by the plan to the participant or beneficiary;

"(2) as part of any yearly informational packet sent to the participant or beneficiary; or

"(3) not later than January 1, 2000;

whichever is earlier.

"(d) SECONDARY CONSULTATIONS.—

"(1) IN GENERAL.—A group health plan that provides coverage with respect to medical and surgical services provided in relation to the diagnosis and treatment of cancer shall ensure that full coverage is provided for secondary consultations by specialists in the appropriate medical fields (including pathology, radiology, and oncology) to confirm or refute such diagnosis. Such plan or issuer shall ensure that full coverage is provided for such secondary consulta-

tion whether such consultation is based on a positive or negative initial diagnosis. In any case in which the attending physician certifies in writing that services necessary for such a secondary consultation are not sufficiently available from specialists operating under the plan with respect to whose services coverage is otherwise provided under such plan or by such issuer, such plan or issuer shall ensure that coverage is provided with respect to the services necessary for the secondary consultation with any other specialist selected by the attending physician for such purpose at no additional cost to the individual beyond that which the individual would have paid if the specialist was participating in the network of the plan.

"(2) EXCEPTION.—Nothing in paragraph (1) shall be construed as requiring the provision of secondary consultations where the patient determines not to seek such a consultation.

"(e) PROHIBITION ON PENALTIES.—A group health plan may not—

"(1) penalize or otherwise reduce or limit the reimbursement of a provider or specialist because the provider or specialist provided care to a participant or beneficiary in accordance with this section;

"(2) provide financial or other incentives to a physician or specialist to induce the physician or specialist to keep the length of inpatient stays of patients following a mastectomy, lumpectomy, or a lymph node dissection for the treatment of breast cancer below certain limits or to limit referrals for secondary consultations; or

"(3) provide financial or other incentives to a physician or specialist to induce the physician or specialist to refrain from referring a participant or beneficiary for a secondary consultation that would otherwise be covered by the plan involved under subsection (d).".

(2) CLERICAL AMENDMENT.—The table of contents for chapter 100 of such Code is amended by inserting after the item relating to section 9813 the following new item:

"Sec. 9814. Required coverage for minimum hospital stay for mastectomies and lymph node dissections for the treatment of breast cancer and coverage for secondary consultations.".

TITLE III—GENETIC INFORMATION AND SERVICES

SEC. 301. SHORT TITLE.

This title may be cited as the "Genetic Information Nondiscrimination in Health Insurance Act of 1999".

SEC. 302. AMENDMENTS TO EMPLOYEE RETIREMENT INCOME SECURITY ACT OF 1974.

(a) PROHIBITION OF HEALTH DISCRIMINATION ON THE BASIS OF GENETIC INFORMATION OR GENETIC SERVICES.—

(1) NO ENROLLMENT RESTRICTION FOR GENETIC SERVICES.—Section 702(a)(1)(F) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1182(a)(1)(F)) is amended by inserting before the period the following: "(including information about a request for or receipt of genetic services)".

(2) NO DISCRIMINATION IN GROUP PREMIUMS BASED ON PREDICTIVE GENETIC INFORMATION.—Subpart B of part 7 of subtitle B of title I of the Employee Retirement Income Security Act of 1974, as amended by sections 111(a) and 201, is further amended by adding at the end the following:

"SEC. 716. PROHIBITING PREMIUM DISCRIMINATION AGAINST GROUPS ON THE BASIS OF PREDICTIVE GENETIC INFORMATION.

"A group health plan, or a health insurance issuer offering group health insurance coverage in connection with a group health plan, shall not adjust premium or contribution amounts for a group on the basis of predictive genetic information concerning any individual (including a dependent) or family member of the individual (including in-

formation about a request for or receipt of genetic services).".

(3) CONFORMING AMENDMENTS.—

(A) IN GENERAL.—Section 702(b) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1182(b)) is amended by adding at the end the following:

"(3) REFERENCE TO RELATED PROVISION.—For a provision prohibiting the adjustment of premium or contribution amounts for a group under a group health plan on the basis of predictive genetic information (including information about a request for or receipt of genetic services), see section 716.".

(B) TABLE OF CONTENTS.—The table of contents in section 1 of the Employee Retirement Income Security Act of 1974, as amended by sections 111(a) and 201, is further amended by inserting after the item relating to section 715 the following new item:

"Sec. 716. Prohibiting premium discrimination against groups on the basis of predictive genetic information.".

(b) LIMITATION ON COLLECTION OF PREDICTIVE GENETIC INFORMATION.—Section 702 of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1182) is amended by adding at the end the following:

"(c) COLLECTION OF PREDICTIVE GENETIC INFORMATION.—

"(1) LIMITATION ON REQUESTING OR REQUIRING PREDICTIVE GENETIC INFORMATION.—Except as provided in paragraph (2), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request or require predictive genetic information concerning any individual (including a dependent) or family member of the individual (including information about a request for or receipt of genetic services).

"(2) INFORMATION NEEDED FOR DIAGNOSIS, TREATMENT, OR PAYMENT.—

"(A) IN GENERAL.—Notwithstanding paragraph (1), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, that provides health care items and services to an individual or dependent may request (but may not require) that such individual or dependent disclose, or authorize the collection or disclosure of, predictive genetic information for purposes of diagnosis, treatment, or payment relating to the provision of health care items and services to such individual or dependent.

"(B) NOTICE OF CONFIDENTIALITY PRACTICES AND DESCRIPTION OF SAFEGUARDS.—As a part of a request under subparagraph (A), the group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall provide to the individual or dependent a description of the procedures in place to safeguard the confidentiality, as described in subsection (d), of such predictive genetic information.

"(d) CONFIDENTIALITY WITH RESPECT TO PREDICTIVE GENETIC INFORMATION.—

"(1) NOTICE OF CONFIDENTIALITY PRACTICES.—

"(A) PREPARATION OF WRITTEN NOTICE.—A group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall post or provide, in writing and in a clear and conspicuous manner, notice of the plan or issuer's confidentiality practices, that shall include—

"(i) a description of an individual's rights with respect to predictive genetic information;

"(ii) the procedures established by the plan or issuer for the exercise of the individual's rights; and

"(iii) the right to obtain a copy of the notice of the confidentiality practices required under this subsection.

"(B) MODEL NOTICE.—The Secretary, in consultation with the National Committee on Vital and Health Statistics and the National Association of Insurance Commissioners, and after notice and opportunity for public comment, shall develop and disseminate model notices of confidentiality practices. Use of the model notice shall serve as a defense against claims of receiving inappropriate notice.

"(2) ESTABLISHMENT OF SAFEGUARDS.—A group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall establish and maintain appropriate administrative, technical, and physical safeguards to protect the confidentiality, security, accuracy, and integrity of predictive genetic information created, received, obtained, maintained, used, transmitted, or disposed of by such plan or issuer.".

(c) DEFINITIONS.—Section 733(d) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1191b(d)) is amended by adding at the end the following:

"(5) FAMILY MEMBER.—The term 'family member' means with respect to an individual—

"(A) the spouse of the individual;

"(B) a dependent child of the individual, including a child who is born to or placed for adoption with the individual; and

"(C) all other individuals related by blood to the individual or the spouse or child described in subparagraph (A) or (B).

"(6) GENETIC INFORMATION.—The term 'genetic information' means information about genes, gene products, or inherited characteristics that may derive from an individual or a family member (including information about a request for or receipt of genetic services).

"(7) GENETIC SERVICES.—The term 'genetic services' means health services provided to obtain, assess, or interpret genetic information for diagnostic and therapeutic purposes, and for genetic education and counseling.

"(8) PREDICTIVE GENETIC INFORMATION.—

"(A) IN GENERAL.—The term 'predictive genetic information' means, in the absence of symptoms, clinical signs, or a diagnosis of the condition related to such information—

"(i) information about an individual's genetic tests;

"(ii) information about genetic tests of family members of the individual; or

"(iii) information about the occurrence of a disease or disorder in family members.

"(B) EXCEPTIONS.—The term 'predictive genetic information' shall not include—

"(i) information about the sex or age of the individual;

"(ii) information derived from physical tests, such as the chemical, blood, or urine analyses of the individual including cholesterol tests; and

"(iii) information about physical exams of the individual.

"(9) GENETIC TEST.—The term 'genetic test' means the analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites, including analysis of genotypes, mutations, phenotypes, or karyotypes, for the purpose of predicting risk of dis-

ease in asymptomatic or undiagnosed individuals. Such term does not include physical tests, such as the chemical, blood, or urine analyses of the individual including cholesterol tests, and physical exams of the individual, in order to detect symptoms, clinical signs, or a diagnosis of disease.".

(d) EFFECTIVE DATE.—Except as provided in this section, this section and the amendments made by this section shall apply with respect to group health plans for plan years beginning 1 year after the date of the enactment of this Act.

SEC. 303. AMENDMENTS TO THE PUBLIC HEALTH SERVICE ACT.

(a) AMENDMENTS RELATING TO THE GROUP MARKET.—

(1) PROHIBITION OF HEALTH DISCRIMINATION ON THE BASIS OF GENETIC INFORMATION IN THE GROUP MARKET.—

(A) NO ENROLLMENT RESTRICTION FOR GENETIC SERVICES.—Section 2702(a)(1)(F) of the Public Health Service Act (42 U.S.C. 300gg–1(a)(1)(F)) is amended by inserting before the period the following: "(including information about a request for or receipt of genetic services)".

(B) NO DISCRIMINATION IN PREMIUMS BASED ON PREDICTIVE GENETIC INFORMATION.—Subpart 2 of part A of title XXVII of the Public Health Service Act, as amended by section 201, is further amended by adding at the end the following new section:

"SEC. 2708. PROHIBITING PREMIUM DISCRIMINATION AGAINST GROUPS ON THE BASIS OF PREDICTIVE GENETIC INFORMATION IN THE GROUP MARKET.

"A group health plan, or a health insurance issuer offering group health insurance coverage in connection with a group health plan shall not adjust premium or contribution amounts for a group on the basis of predictive genetic information concerning any individual (including a dependent) or family member of the individual (including information about a request for or receipt of genetic services).".

(C) CONFORMING AMENDMENT.—Section 2702(b) of the Public Health Service Act (42 U.S.C. 300gg–1(b)) is amended by adding at the end the following:

"(3) REFERENCE TO RELATED PROVISION.—For a provision prohibiting the adjustment of premium or contribution amounts for a group under a group

health plan on the basis of predictive genetic information (including information about a request for or receipt of genetic services), see section 2708.".

(D) LIMITATION ON COLLECTION AND DISCLOSURE OF PREDICTIVE GENETIC INFORMATION.—Section 2702 of the Public Health Service Act (42 U.S.C. 300gg–1) is amended by adding at the end the following:

"(c) COLLECTION OF PREDICTIVE GENETIC INFORMATION.—

"(1) LIMITATION ON REQUESTING OR REQUIRING PREDICTIVE GENETIC INFORMATION.—Except as provided in paragraph (2), a group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall not request or require predictive genetic information concerning any individual (including a dependent) or a family member of the individual (including information about a request for or receipt of genetic services).

"(2) INFORMATION NEEDED FOR DIAGNOSIS, TREATMENT, OR PAYMENT.—

"(A) IN GENERAL.—Notwithstanding paragraph (1), a group health plan, or a health insurance issuer offering health insurance coverage

in connection with a group health plan, that provides health care items and services to an individual or dependent may request (but may not require) that such individual or dependent disclose, or authorize the collection or disclosure of, predictive genetic information for purposes of diagnosis, treatment, or payment relating to the provision of health care items and services to such individual or dependent.

"(B) NOTICE OF CONFIDENTIALITY PRACTICES AND DESCRIPTION OF SAFEGUARDS.—As a part of a request under subparagraph (A), the group health plan, or a health insurance issuer offering health insurance coverage in connection with a group health plan, shall provide to the individual or dependent a description of the procedures in place to safeguard the confidentiality, as described in subsection (d), of such predictive genetic information.

"(d) CONFIDENTIALITY WITH RESPECT TO PREDICTIVE GENETIC INFORMATION.—

"(1) NOTICE OF CONFIDENTIALITY PRACTICES.—

"(A) PREPARATION OF WRITTEN NOTICE.—A group health plan, or a health insurance issuer offering health insurance coverage in con-

nection with a group health plan, shall post or provide, in writing and in a clear and conspicuous manner, notice of the plan or issuer's confidentiality practices, that shall include—

"(i) a description of an individual's rights with respect to predictive genetic information;

"(ii) the procedures established by the plan or issuer for the exercise of the individual's rights; and

"(iii) the right to obtain a copy of the notice of the confidentiality practices required under this subsection.

"(B) MODEL NOTICE.—The Secretary, in consultation with the National Committee on Vital and Health Statistics and the National Association of Insurance Commissioners, and after notice and opportunity for public comment, shall develop and disseminate model notices of confidentiality practices. Use of the model notice shall serve as a defense against claims of receiving inappropriate notice.

"(2) ESTABLISHMENT OF SAFEGUARDS.—A group health plan, or a health insurance issuer offering health insurance coverage in connection with a

group health plan, shall establish and maintain appropriate administrative, technical, and physical safeguards to protect the confidentiality, security, accuracy, and integrity of predictive genetic information created, received, obtained, maintained, used, transmitted, or disposed of by such plan or issuer.".

(2) DEFINITIONS.—Section 2791(d) of the Public Health Service Act (42 U.S.C. 300gg–91(d)) is amended by adding at the end the following:

"(15) FAMILY MEMBER.—The term 'family member' means, with respect to an individual—

"(A) the spouse of the individual;

"(B) a dependent child of the individual, including a child who is born to or placed for adoption with the individual; and

"(C) all other individuals related by blood to the individual or the spouse or child described in subparagraph (A) or (B).

"(16) GENETIC INFORMATION.—The term 'genetic information' means information about genes, gene products, or inherited characteristics that may derive from an individual or a family member (including information about a request for or receipt of genetic services).

"(17) GENETIC SERVICES.—The term 'genetic services' means health services provided to obtain, assess, or interpret genetic information for diagnostic and therapeutic purposes, and for genetic education and counseling.

"(18) PREDICTIVE GENETIC INFORMATION.—

"(A) IN GENERAL.—The term 'predictive genetic information' means, in the absence of symptoms, clinical signs, or a diagnosis of the condition related to such information—

"(i) information about an individual's genetic tests;

"(ii) information about genetic tests of family members of the individual; or

"(iii) information about the occurrence of a disease or disorder in family members.

"(B) EXCEPTIONS.—The term 'predictive genetic information' shall not include—

"(i) information about the sex or age of the individual;

"(ii) information derived from physical tests, such as the chemical, blood, or urine analyses of the individual including cholesterol tests; and

"(iii) information about physical exams of the individual.

"(19) GENETIC TEST.—The term 'genetic test' means the analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites, including analysis of genotypes, mutations, phenotypes, or karyotypes, for the purpose of predicting risk of disease in asymptomatic or undiagnosed individuals. Such term does not include physical tests, such as the chemical, blood, or urine analyses of the individual including cholesterol tests, and physical exams of the individual, in order to detect symptoms, clinical signs, or a diagnosis of disease.".

(b) AMENDMENT RELATING TO THE INDIVIDUAL MARKET.—Subpart 2 of part B of title XXVII of the Public Health Service Act, as amended by section 201, is further amended by adding at the end the following new section:

"SEC. 2754. PROHIBITION OF HEALTH DISCRIMINATION ON THE BASIS OF PREDICTIVE GENETIC INFORMATION.

"(a) PROHIBITION ON PREDICTIVE GENETIC INFORMATION AS A CONDITION OF ELIGIBILITY.—A health insurance issuer offering health insurance coverage in the individual market may not use predictive genetic information as a condition of eligibility of an individual to enroll in indi-

vidual health insurance coverage (including information about a request for or receipt of genetic services).

"(b) PROHIBITION ON PREDICTIVE GENETIC INFORMATION IN SETTING PREMIUM RATES.—A health insurance issuer offering health insurance coverage in the individual market shall not adjust premium rates for individuals on the basis of predictive genetic information concerning such an individual (including a dependent) or a family member of the individual (including information about a request for or receipt of genetic services).

"(c) COLLECTION OF PREDICTIVE GENETIC INFORMATION.—

"(1) LIMITATION ON REQUESTING OR REQUIRING PREDICTIVE GENETIC INFORMATION.—Except as provided in paragraph (2), a health insurance issuer offering health insurance coverage in the individual market shall not request or require predictive genetic information concerning any individual (including a dependent) or a family member of the individual (including information about a request for or receipt of genetic services).

"(2) INFORMATION NEEDED FOR DIAGNOSIS, TREATMENT, OR PAYMENT.—

"(A) IN GENERAL.—Notwithstanding paragraph (1), a health insurance issuer offering

health insurance coverage in the individual market that provides health care items and services to an individual or dependent may request (but may not require) that such individual or dependent disclose, or authorize the collection or disclosure of, predictive genetic information for purposes of diagnosis, treatment, or payment relating to the provision of health care items and services to such individual or dependent.

"(B) NOTICE OF CONFIDENTIALITY PRACTICES AND DESCRIPTION OF SAFEGUARDS.—As a part of a request under subparagraph (A), the health insurance issuer offering health insurance coverage in the individual market shall provide to the individual or dependent a description of the procedures in place to safeguard the confidentiality, as described in subsection (d), of such predictive genetic information.

"(d) CONFIDENTIALITY WITH RESPECT TO PREDICTIVE GENETIC INFORMATION.—

"(1) NOTICE OF CONFIDENTIALITY PRACTICES.—

"(A) PREPARATION OF WRITTEN NOTICE.—A health insurance issuer offering health insurance coverage in the individual market shall post or provide, in writing and in a clear and con-

spicuous manner, notice of the issuer's confidentiality practices, that shall include—

"(i) a description of an individual's rights with respect to predictive genetic information;

"(ii) the procedures established by the issuer for the exercise of the individual's rights; and

"(iii) the right to obtain a copy of the notice of the confidentiality practices required under this subsection.

"(B) MODEL NOTICE.—The Secretary, in consultation with the National Committee on Vital and Health Statistics and the National Association of Insurance Commissioners, and after notice and opportunity for public comment, shall develop and disseminate model notices of confidentiality practices. Use of the model notice shall serve as a defense against claims of receiving inappropriate notice.

"(2) ESTABLISHMENT OF SAFEGUARDS.—A health insurance issuer offering health insurance coverage in the individual market shall establish and maintain appropriate administrative, technical, and physical safeguards to protect the confidentiality, se-

curity, accuracy, and integrity of predictive genetic information created, received, obtained, maintained, used, transmitted, or disposed of by such issuer.".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply with respect to—

(1) group health plans, and health insurance coverage offered in connection with group health plans, for plan years beginning after 1 year after the date of enactment of this Act; and

(2) health insurance coverage offered, sold, issued, renewed, in effect, or operated in the individual market after 1 year after the date of enactment of this Act.

SEC. 304. AMENDMENTS TO THE INTERNAL REVENUE CODE OF 1986.

(a) PROHIBITION OF HEALTH DISCRIMINATION ON THE BASIS OF GENETIC INFORMATION OR GENETIC SERVICES.—

(1) NO ENROLLMENT RESTRICTION FOR GENETIC SERVICES.—Section 9802(a)(1)(F) of the Internal Revenue Code of 1986 is amended by inserting before the period the following: "(including information about a request for or receipt of genetic services)".

(2) NO DISCRIMINATION IN GROUP PREMIUMS BASED ON PREDICTIVE GENETIC INFORMATION.—

(A) IN GENERAL.—Subchapter B of chapter 100 of the Internal Revenue Code of 1986, as amended by sections 111(b) and 201, is further amended by adding at the end the following:

"SEC. 9815. PROHIBITING PREMIUM DISCRIMINATION AGAINST GROUPS ON THE BASIS OF PREDICTIVE GENETIC INFORMATION.

"A group health plan shall not adjust premium or contribution amounts for a group on the basis of predictive genetic information concerning any individual (including a dependent) or a family member of the individual (including information about a request for or receipt of genetic services).".

(B) CONFORMING AMENDMENT.—Section 9802(b) of the Internal Revenue Code of 1986 is amended by adding at the end the following:

"(3) REFERENCE TO RELATED PROVISION.—For a provision prohibiting the adjustment of premium or contribution amounts for a group under a group health plan on the basis of predictive genetic information (including information about a request for or the receipt of genetic services), see section 9815.".

(C) AMENDMENT TO TABLE OF SECTIONS.—The table of sections for subchapter B of chapter 100 of the Internal Revenue Code of 1986, as

amended by sections 111(b) and 201, is further amended by adding at the end the following:

"Sec. 9816. Prohibiting premium discrimination against groups on the basis of predictive genetic information.".

(b) LIMITATION ON COLLECTION OF PREDICTIVE GENETIC INFORMATION.—Section 9802 of the Internal Revenue Code of 1986 is amended by adding at the end the following:

"(d) COLLECTION OF PREDICTIVE GENETIC INFORMATION.—

"(1) LIMITATION ON REQUESTING OR REQUIRING PREDICTIVE GENETIC INFORMATION.—Except as provided in paragraph (2), a group health plan shall not request or require predictive genetic information concerning any individual (including a dependent) or a family member of the individual (including information about a request for or receipt of genetic services).

"(2) INFORMATION NEEDED FOR DIAGNOSIS, TREATMENT, OR PAYMENT.—

"(A) IN GENERAL.—Notwithstanding paragraph (1), a group health plan that provides health care items and services to an individual or dependent may request (but may not require) that such individual or dependent disclose, or authorize the collection or disclosure of, predictive genetic information for purposes of diag-

nosis, treatment, or payment relating to the provision of health care items and services to such individual or dependent.

"(B) NOTICE OF CONFIDENTIALITY PRACTICES; DESCRIPTION OF SAFEGUARDS.—As a part of a request under subparagraph (A), the group health plan shall provide to the individual or dependent a description of the procedures in place to safeguard the confidentiality, as described in subsection (e), of such predictive genetic information.

"(e) CONFIDENTIALITY WITH RESPECT TO PREDICTIVE GENETIC INFORMATION.—

"(1) NOTICE OF CONFIDENTIALITY PRACTICES.—

"(A) PREPARATION OF WRITTEN NOTICE.—A group health plan shall post or provide, in writing and in a clear and conspicuous manner, notice of the plan's confidentiality practices, that shall include—

"(i) a description of an individual's rights with respect to predictive genetic information;

"(ii) the procedures established by the plan for the exercise of the individual's rights; and

"(iii) the right to obtain a copy of the notice of the confidentiality practices required under this subsection.

"(B) MODEL NOTICE.—The Secretary, in consultation with the National Committee on Vital and Health Statistics and the National Association of Insurance Commissioners, and after notice and opportunity for public comment, shall develop and disseminate model notices of confidentiality practices. Use of the model notice shall serve as a defense against claims of receiving inappropriate notice.

"(2) ESTABLISHMENT OF SAFEGUARDS.—A group health plan shall establish and maintain appropriate administrative, technical, and physical safeguards to protect the confidentiality, security, accuracy, and integrity of predictive genetic information created, received, obtained, maintained, used, transmitted, or disposed of by such plan.".

(c) DEFINITIONS.—Section 9832(d) of the Internal Revenue Code of 1986 is amended by adding at the end the following:

"(6) FAMILY MEMBER.—The term 'family member' means, with respect to an individual—

"(A) the spouse of the individual;

"(B) a dependent child of the individual, including a child who is born to or placed for adoption with the individual; and

"(C) all other individuals related by blood to the individual or the spouse or child described in subparagraph (A) or (B).

"(7) GENETIC INFORMATION.—The term 'genetic information' means information about genes, gene products, or inherited characteristics that may derive from an individual or a family member (including information about a request for or receipt of genetic services).

"(8) GENETIC SERVICES.—The term 'genetic services' means health services provided to obtain, assess, or interpret genetic information for diagnostic and therapeutic purposes, and for genetic education and counseling.

"(9) PREDICTIVE GENETIC INFORMATION.—

"(A) IN GENERAL.—The term 'predictive genetic information' means, in the absence of symptoms, clinical signs, or a diagnosis of the condition related to such information—

"(i) information about an individual's genetic tests;

"(ii) information about genetic tests of family members of the individual; or

"(iii) information about the occurrence of a disease or disorder in family members.

"(B) EXCEPTIONS.—The term 'predictive genetic information' shall not include—

"(i) information about the sex or age of the individual;

"(ii) information derived from physical tests, such as the chemical, blood, or urine analyses of the individual including cholesterol tests; and

"(iii) information about physical exams of the individual.

"(10) GENETIC TEST.—The term 'genetic test' means the analysis of human DNA, RNA, chromosomes, proteins, and certain metabolites, including analysis of genotypes, mutations, phenotypes, or karyotypes, for the purpose of predicting risk of disease in asymptomatic or undiagnosed individuals. Such term does not include physical tests, such as the chemical, blood, or urine analyses of the individual including cholesterol tests, and physical exams of the individual, in order to detect symptoms, clinical signs, or a diagnosis of disease.".

(d) EFFECTIVE DATE.—Except as provided in this section, this section and the amendments made by this section shall apply with respect to group health plans for plan years beginning after 1 year after the date of the enactment of this Act.

TITLE IV—HEALTHCARE RESEARCH AND QUALITY

SEC. 401. SHORT TITLE.

This title may be cited as the "Healthcare Research and Quality Act of 1999".

SEC. 402. AMENDMENT TO THE PUBLIC HEALTH SERVICE ACT.

Title IX of the Public Health Service Act (42 U.S.C. 299 et seq.) is amended to read as follows:

"TITLE IX—AGENCY FOR HEALTHCARE RESEARCH AND QUALITY

"PART A—ESTABLISHMENT AND GENERAL DUTIES

"SEC. 901. MISSION AND DUTIES.

"(a) IN GENERAL.—There is established within the Public Health Service an agency to be known as the Agency for Healthcare Research and Quality. In carrying out this subsection, the Secretary shall redesignate the Agency for

Health Care Policy and Research as the Agency for Healthcare Research and Quality.

"(b) MISSION.—The purpose of the Agency is to enhance the quality, appropriateness, and effectiveness of healthcare services, and access to such services, through the establishment of a broad base of scientific research and through the promotion of improvements in clinical and health system practices, including the prevention of diseases and other health conditions. The Agency shall promote healthcare quality improvement by—

"(1) conducting and supporting research that develops and presents scientific evidence regarding all aspects of healthcare, including—

"(A) the development and assessment of methods for enhancing patient participation in their own care and for facilitating shared patient-physician decision-making;

"(B) the outcomes, effectiveness, and cost-effectiveness of healthcare practices, including preventive measures and long-term care;

"(C) existing and innovative technologies;

"(D) the costs and utilization of, and access to healthcare;

"(E) the ways in which healthcare services are organized, delivered, and financed and the

interaction and impact of these factors on the quality of patient care;

"(F) methods for measuring quality and strategies for improving quality; and

"(G) ways in which patients, consumers, purchasers, and practitioners acquire new information about best practices and health benefits, the determinants and impact of their use of this information;

"(2) synthesizing and disseminating available scientific evidence for use by patients, consumers, practitioners, providers, purchasers, policy makers, and educators; and

"(3) advancing private and public efforts to improve healthcare quality.

"(c) REQUIREMENTS WITH RESPECT TO RURAL AREAS AND PRIORITY POPULATIONS.—In carrying out subsection (b), the Director shall undertake and support research, demonstration projects, and evaluations with respect to the delivery of health services—

"(1) in rural areas (including frontier areas);

"(2) for low-income groups, and minority groups;

"(3) for children;

"(4) for elderly; and

"(5) for people with special healthcare needs, including disabilities, chronic care and end-of-life healthcare.

"(d) APPOINTMENT OF DIRECTOR.—There shall be at the head of the Agency an official to be known as the Director for Healthcare Research and Quality. The Director shall be appointed by the Secretary. The Secretary, acting through the Director, shall carry out the authorities and duties established in this title.

"SEC. 902. GENERAL AUTHORITIES.

"(a) IN GENERAL.—In carrying out section 901(b), the Director shall support demonstration projects, conduct and support research, evaluations, training, research networks, multi-disciplinary centers, technical assistance, and the dissemination of information, on healthcare, and on systems for the delivery of such care, including activities with respect to—

"(1) the quality, effectiveness, efficiency, appropriateness and value of healthcare services;

"(2) quality measurement and improvement;

"(3) the outcomes, cost, cost-effectiveness, and use of healthcare services and access to such services;

"(4) clinical practice, including primary care and practice-oriented research;

"(5) healthcare technologies, facilities, and equipment;

"(6) healthcare costs, productivity, organization, and market forces;

"(7) health promotion and disease prevention, including clinical preventive services;

"(8) health statistics, surveys, database development, and epidemiology; and

"(9) medical liability.

"(b) HEALTH SERVICES TRAINING GRANTS.—

"(1) IN GENERAL.—The Director may provide training grants in the field of health services research related to activities authorized under subsection (a), to include pre- and post-doctoral fellowships and training programs, young investigator awards, and other programs and activities as appropriate. In carrying out this subsection, the Director shall make use of funds made available under section 487 as well as other appropriated funds.

"(2) REQUIREMENTS.—In developing priorities for the allocation of training funds under this subsection, the Director shall take into consideration shortages in the number of trained researchers addressing the priority populations.

"(c) MULTIDISCIPLINARY CENTERS.—The Director may provide financial assistance to assist in meeting the costs of planning and establishing new centers, and operating existing and new centers, for multidisciplinary health services research, demonstration projects, evaluations, training, and policy analysis with respect to the matters referred to in subsection (a).

"(d) RELATION TO CERTAIN AUTHORITIES REGARDING SOCIAL SECURITY.—Activities authorized in this section shall be appropriately coordinated with experiments, demonstration projects, and other related activities authorized by the Social Security Act and the Social Security Amendments of 1967. Activities under subsection (a)(2) of this section that affect the programs under titles XVIII, XIX and XXI of the Social Security Act shall be carried out consistent with section 1142 of such Act.

"(e) DISCLAIMER.—The Agency shall not mandate national standards of clinical practice or quality healthcare standards. Recommendations resulting from projects funded and published by the Agency shall include a corresponding disclaimer.

"(f) RULE OF CONSTRUCTION.—Nothing in this section shall be construed to imply that the Agency's role is to mandate a national standard or specific approach to quality measurement and reporting. In research and qual-

ity improvement activities, the Agency shall consider a wide range of choices, providers, healthcare delivery systems, and individual preferences.

"PART B—HEALTHCARE IMPROVEMENT RESEARCH

"SEC. 911. HEALTHCARE OUTCOME IMPROVEMENT RESEARCH.

"(a) EVIDENCE RATING SYSTEMS.—In collaboration with experts from the public and private sector, the Agency shall identify and disseminate methods or systems that it uses to assess healthcare research results, particularly methods or systems that it uses to rate the strength of the scientific evidence behind healthcare practice, recommendations in the research literature, and technology assessments. The Agency shall make methods and systems for evidence rating widely available. Agency publications containing healthcare recommendations shall indicate the level of substantiating evidence using such methods or systems.

"(b) HEALTHCARE IMPROVEMENT RESEARCH CENTERS AND PROVIDER-BASED RESEARCH NETWORKS.—In order to address the full continuum of care and outcomes research, to link research to practice improvement, and to speed the dissemination of research findings to community practice settings, the Agency shall employ research strategies and mechanisms that will link research directly with

clinical practice in geographically diverse locations throughout the United States, including—

"(1) Healthcare Improvement Research Centers that combine demonstrated multidisciplinary expertise in outcomes or quality improvement research with linkages to relevant sites of care;

"(2) Provider-based Research Networks, including plan, facility, or delivery system sites of care (especially primary care), that can evaluate and promote quality improvement; and

"(3) other innovative mechanisms or strategies to link research with clinical practice.

"SEC. 912. PRIVATE-PUBLIC PARTNERSHIPS TO IMPROVE ORGANIZATION AND DELIVERY.

"(a) SUPPORT FOR EFFORTS TO DEVELOP INFORMATION ON QUALITY.—

"(1) SCIENTIFIC AND TECHNICAL SUPPORT.—In its role as the principal agency for healthcare research and quality, the Agency may provide scientific and technical support for private and public efforts to improve healthcare quality, including the activities of accrediting organizations.

"(2) ROLE OF THE AGENCY.—With respect to paragraph (1), the role of the Agency shall include—

"(A) the identification and assessment of methods for the evaluation of the health of—

"(i) enrollees in health plans by type of plan, provider, and provider arrangements; and

"(ii) other populations, including those receiving long-term care services;

"(B) the ongoing development, testing, and dissemination of quality measures, including measures of health and functional outcomes;

"(C) the compilation and dissemination of healthcare quality measures developed in the private and public sector;

"(D) assistance in the development of improved healthcare information systems;

"(E) the development of survey tools for the purpose of measuring participant and beneficiary assessments of their healthcare; and

"(F) identifying and disseminating information on mechanisms for the integration of information on quality into purchaser and consumer decision-making processes.

"(b) CENTERS FOR EDUCATION AND RESEARCH ON THERAPEUTICS.—

"(1) IN GENERAL.—The Secretary, acting through the Director and in consultation with the Commissioner of Food and Drugs, shall establish a program for the purpose of making one or more grants for the establishment and operation of one or more centers to carry out the activities specified in paragraph (2).

"(2) REQUIRED ACTIVITIES.—The activities referred to in this paragraph are the following:

"(A) The conduct of state-of-the-art clinical, laboratory, or health services research for the following purposes:

"(i) To increase awareness of—

"(I) new uses of drugs, biological products, and devices;

"(II) ways to improve the effective use of drugs, biological products, and devices; and

"(III) risks of new uses and risks of combinations of drugs and biological products.

"(ii) To provide objective clinical information to the following individuals and entities:

"(I) Healthcare practitioners and other providers of healthcare goods or services.

"(II) Pharmacists, pharmacy benefit managers and purchasers.

"(III) Health maintenance organizations and other managed healthcare organizations.

"(IV) Healthcare insurers and governmental agencies.

"(V) Patients and consumers.

"(iii) To improve the quality of healthcare while reducing the cost of Healthcare through—

"(I) an increase in the appropriate use of drugs, biological products, or devices; and

"(II) the prevention of adverse effects of drugs, biological products, and devices and the consequences of such effects, such as unnecessary hospitalizations.

"(B) The conduct of research on the comparative effectiveness, cost-effectiveness, and safety of drugs, biological products, and devices.

"(C) Such other activities as the Secretary determines to be appropriate, except that grant funds may not be used by the Secretary in conducting regulatory review of new drugs.

"(c) REDUCING ERRORS IN MEDICINE.—The Director shall conduct and support research and build private-public partnerships to—

"(1) identify the causes of preventable healthcare errors and patient injury in healthcare delivery;

"(2) develop, demonstrate, and evaluate strategies for reducing errors and improving patient safety; and

"(3) promote the implementation of effective strategies throughout the healthcare industry.

"SEC. 913. INFORMATION ON QUALITY AND COST OF CARE.

"(a) IN GENERAL.—In carrying out 902(a), the Director shall—

"(1) conduct a survey to collect data on a nationally representative sample of the population on the cost, use and, for fiscal year 2001 and subsequent fiscal years, quality of healthcare, including the types of healthcare services Americans use, their access to healthcare services, frequency of use, how much is paid for the services used, the source of those payments, the types and costs of private health insurance,

access, satisfaction, and quality of care for the general population including rural residents and for the populations identified in section 901(c); and

"(2) develop databases and tools that provide information to States on the quality, access, and use of healthcare services provided to their residents.

"(b) QUALITY AND OUTCOMES INFORMATION.—

"(1) IN GENERAL.—Beginning in fiscal year 2001, the Director shall ensure that the survey conducted under subsection (a)(1) will—

"(A) identify determinants of health outcomes and functional status, and their relationships to healthcare access and use, determine the ways and extent to which the priority populations enumerated in section 901(c) differ from the general population with respect to such variables, measure changes over time with respect to such variable, and monitor the overall national impact of changes in Federal and State policy on healthcare;

"(B) provide information on the quality of care and patient outcomes for frequently occurring clinical conditions for a nationally representative sample of the population including rural residents; and

"(C) provide reliable national estimates for children and persons with special healthcare needs through the use of supplements or periodic expansions of the survey.

In expanding the Medical Expenditure Panel Survey, as in existence on the date of enactment of this title, in fiscal year 2001 to collect information on the quality of care, the Director shall take into account any outcomes measurements generally collected by private sector accreditation organizations.

"(2) ANNUAL REPORT.—Beginning in fiscal year 2003, the Secretary, acting through the Director, shall submit to Congress an annual report on national trends in the quality of healthcare provided to the American people.

"SEC. 914. INFORMATION SYSTEMS FOR HEALTHCARE IMPROVEMENT.

"(a) IN GENERAL.—In order to foster a range of innovative approaches to the management and communication of health information, the Agency shall support research, evaluations and initiatives to advance—

"(1) the use of information systems for the study of healthcare quality, including the generation of both individual provider and plan-level comparative performance data;

"(2) training for healthcare practitioners and researchers in the use of information systems;

"(3) the creation of effective linkages between various sources of health information, including the development of information networks;

"(4) the delivery and coordination of evidence-based healthcare services, including the use of real-time healthcare decision-support programs;

"(5) the utility and comparability of health information data and medical vocabularies by addressing issues related to the content, structure, definitions and coding of such information and data in consultation with appropriate Federal, State and private entities;

"(6) the use of computer-based health records in all settings for the development of personal health records for individual health assessment and maintenance, and for monitoring public health and outcomes of care within populations; and

"(7) the protection of individually identifiable information in health services research and healthcare quality improvement.

"(b) DEMONSTRATION.—The Agency shall support demonstrations into the use of new information tools aimed

at improving shared decision-making between patients and their care-givers.

"SEC. 915. RESEARCH SUPPORTING PRIMARY CARE AND ACCESS IN UNDERSERVED AREAS.

"(a) PREVENTIVE SERVICES TASK FORCE.—

"(1) ESTABLISHMENT AND PURPOSE.—The Director may periodically convene a Preventive Services Task Force to be composed of individuals with appropriate expertise. Such a task force shall review the scientific evidence related to the effectiveness, appropriateness, and cost-effectiveness of clinical preventive services for the purpose of developing recommendations for the healthcare community, and updating previous clinical preventive recommendations.

"(2) ROLE OF AGENCY.—The Agency shall provide ongoing administrative, research, and technical support for the operations of the Preventive Services Task Force, including coordinating and supporting the dissemination of the recommendations of the Task Force.

"(3) OPERATION.—In carrying out its responsibilities under paragraph (1), the Task Force is not subject to the provisions of Appendix 2 of title 5, United States Code.

"(b) PRIMARY CARE RESEARCH.—

"(1) IN GENERAL.—There is established within the Agency a Center for Primary Care Research (referred to in this subsection as the 'Center') that shall serve as the principal source of funding for primary care practice research in the Department of Health and Human Services. For purposes of this paragraph, primary care research focuses on the first contact when illness or health concerns arise, the diagnosis, treatment or referral to specialty care, preventive care, and the relationship between the clinician and the patient in the context of the family and community.

"(2) RESEARCH.—In carrying out this section, the Center shall conduct and support research concerning—

"(A) the nature and characteristics of primary care practice;

"(B) the management of commonly occurring clinical problems;

"(C) the management of undifferentiated clinical problems; and

"(D) the continuity and coordination of health services.

"SEC. 916. CLINICAL PRACTICE AND TECHNOLOGY INNOVATION.

"(a) IN GENERAL.—The Director shall promote innovation in evidence-based clinical practice and healthcare technologies by—

"(1) conducting and supporting research on the development, diffusion, and use of healthcare technology;

"(2) developing, evaluating, and disseminating methodologies for assessments of healthcare practices and healthcare technologies;

"(3) conducting intramural and supporting extramural assessments of existing and new healthcare practices and technologies;

"(4) promoting education, training, and providing technical assistance in the use of healthcare practice and healthcare technology assessment methodologies and results; and

"(5) working with the National Library of Medicine and the public and private sector to develop an electronic clearinghouse of currently available assessments and those in progress.

"(b) SPECIFICATION OF PROCESS.—

"(1) IN GENERAL.—Not later than December 31, 2000, the Director shall develop and publish a description of the methodology used by the Agency and

its contractors in conducting practice and technology assessment.

"(2) CONSULTATIONS.—In carrying out this subsection, the Director shall cooperate and consult with the Assistant Secretary for Health, the Administrator of the Health Care Financing Administration, the Director of the National Institutes of Health, the Commissioner of Food and Drugs, and the heads of any other interested Federal department or agency, and shall seek input, where appropriate, from professional societies and other private and public entities.

"(3) METHODOLOGY.—The Director, in developing assessment methodology, shall consider—

"(A) safety, efficacy, and effectiveness;

"(B) legal, social, and ethical implications;

"(C) costs, benefits, and cost-effectiveness;

"(D) comparisons to alternate technologies and practices; and

"(E) requirements of Food and Drug Administration approval to avoid duplication.

"(c) SPECIFIC ASSESSMENTS.—

"(1) IN GENERAL.—The Director shall conduct or support specific assessments of healthcare technologies and practices.

"(2) REQUESTS FOR ASSESSMENTS.—The Director is authorized to conduct or support assessments, on a reimbursable basis, for the Health Care Financing Administration, the Department of Defense, the Department of Veterans Affairs, the Office of Personnel Management, and other public or private entities.

"(3) GRANTS AND CONTRACTS.—In addition to conducting assessments, the Director may make grants to, or enter into cooperative agreements or contracts with, entities described in paragraph (4) for the purpose of conducting assessments of experimental, emerging, existing, or potentially outmoded healthcare technologies, and for related activities.

"(4) ELIGIBLE ENTITIES.—An entity described in this paragraph is an entity that is determined to be appropriate by the Director, including academic medical centers, research institutions and organizations, professional organizations, third party payers, governmental agencies, and consortia of appropriate research entities established for the purpose of conducting technology assessments.

"SEC. 917. COORDINATION OF FEDERAL GOVERNMENT QUALITY IMPROVEMENT EFFORTS.

"(a) REQUIREMENT.—

"(1) IN GENERAL.—To avoid duplication and ensure that Federal resources are used efficiently and effectively, the Secretary, acting through the Director, shall coordinate all research, evaluations, and demonstrations related to health services research, quality measurement and quality improvement activities undertaken and supported by the Federal Government.

"(2) SPECIFIC ACTIVITIES.—The Director, in collaboration with the appropriate Federal officials representing all concerned executive agencies and departments, shall develop and manage a process to—

"(A) improve interagency coordination, priority setting, and the use and sharing of research findings and data pertaining to Federal quality improvement programs, technology assessment, and health services research;

"(B) strengthen the research information infrastructure, including databases, pertaining to Federal health services research and healthcare quality improvement initiatives;

"(C) set specific goals for participating agencies and departments to further health services research and healthcare quality improvement; and

"(D) strengthen the management of Federal healthcare quality improvement programs.

"(b) STUDY BY THE INSTITUTE OF MEDICINE.—

"(1) IN GENERAL.—To provide Congress, the Department of Health and Human Services, and other relevant departments with an independent, external review of their quality oversight, quality improvement and quality research programs, the Secretary shall enter into a contract with the Institute of Medicine—

"(A) to describe and evaluate current quality improvement, quality research and quality monitoring processes through—

"(i) an overview of pertinent health services research activities and quality improvement efforts conducted by all Federal programs, with particular attention paid to those under titles XVIII, XIX, and XXI of the Social Security Act; and

"(ii) a summary of the partnerships that the Department of Health and Human Services has pursued with private accreditation, quality measurement and improvement organizations; and

"(B) to identify options and make recommendations to improve the efficiency and ef-

fectiveness of quality improvement programs through—

"(i) the improved coordination of activities across the medicare, medicaid and child health insurance programs under titles XVIII, XIX and XXI of the Social Security Act and health services research programs;

"(ii) the strengthening of patient choice and participation by incorporating state-of-the-art quality monitoring tools and making information on quality available; and

"(iii) the enhancement of the most effective programs, consolidation as appropriate, and elimination of duplicative activities within various federal agencies.

"(2) REQUIREMENTS.—

"(A) IN GENERAL.—The Secretary shall enter into a contract with the Institute of Medicine for the preparation—

"(i) not later than 12 months after the date of enactment of this title, of a report providing an overview of the quality improvement programs of the Department of Health and Human Services for the medicare, medicaid, and CHIP programs under

titles XVIII, XIX, and XXI of the Social Security Act; and

"(ii) not later than 24 months after the date of enactment of this title, of a final report containing recommendations.

"(B) REPORTS.—The Secretary shall submit the reports described in subparagraph (A) to the Committee on Finance and the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Ways and Means and the Committee on Commerce of the House of Representatives.

"PART C—GENERAL PROVISIONS

"SEC. 921. ADVISORY COUNCIL FOR HEALTHCARE RESEARCH AND QUALITY.

"(a) ESTABLISHMENT.—There is established an advisory council to be known as the Advisory Council for Healthcare Research and Quality.

"(b) DUTIES.—

"(1) IN GENERAL.—The Advisory Council shall advise the Secretary and the Director with respect to activities proposed or undertaken to carry out the purpose of the Agency under section 901(b).

"(2) CERTAIN RECOMMENDATIONS.—Activities of the Advisory Council under paragraph (1) shall in-

clude making recommendations to the Director regarding—

"(A) priorities regarding healthcare research, especially studies related to quality, outcomes, cost and the utilization of, and access to, healthcare services;

"(B) the field of healthcare research and related disciplines, especially issues related to training needs, and dissemination of information pertaining to healthcare quality; and

"(C) the appropriate role of the Agency in each of these areas in light of private sector activity and identification of opportunities for public-private sector partnerships.

"(c) MEMBERSHIP.—

"(1) IN GENERAL.—The Advisory Council shall, in accordance with this subsection, be composed of appointed members and ex officio members. All members of the Advisory Council shall be voting members other than the individuals designated under paragraph (3)(B) as ex officio members.

"(2) APPOINTED MEMBERS.—The Secretary shall appoint to the Advisory Council 21 appropriately qualified individuals. At least 17 members of the Advisory Council shall be representatives of the public

who are not officers or employees of the United States. The Secretary shall ensure that the appointed members of the Council, as a group, are representative of professions and entities concerned with, or affected by, activities under this title and under section 1142 of the Social Security Act. Of such members—

"(A) 4 shall be individuals distinguished in the conduct of research, demonstration projects, and evaluations with respect to healthcare;

"(B) 4 shall be individuals distinguished in the practice of medicine of which at least 1 shall be a primary care practitioner;

"(C) 3 shall be individuals distinguished in the other health professions;

"(D) 4 shall be individuals either representing the private healthcare sector, including health plans, providers, and purchasers or individuals distinguished as administrators of healthcare delivery systems;

"(E) 4 shall be individuals distinguished in the fields of healthcare quality improvement, economics, information systems, law, ethics, business, or public policy, including at least 1 individual specializing in rural aspects in 1 or more of these fields; and

"(F) 2 shall be individuals representing the interests of patients and consumers of healthcare.

"(3) EX OFFICIO MEMBERS.—The Secretary shall designate as ex officio members of the Advisory Council—

"(A) the Assistant Secretary for Health, the Director of the National Institutes of Health, the Director of the Centers for Disease Control and Prevention, the Administrator of the Health Care Financing Administration, the Assistant Secretary of Defense (Health Affairs), and the Under Secretary for Health of the Department of Veterans Affairs; and

"(B) such other Federal officials as the Secretary may consider appropriate.

"(d) TERMS.—Members of the Advisory Council appointed under subsection (c)(2) shall serve for a term of 3 years. A member of the Council appointed under such subsection may continue to serve after the expiration of the term of the members until a successor is appointed.

"(e) VACANCIES.—If a member of the Advisory Council appointed under subsection (c)(2) does not serve the full term applicable under subsection (d), the individual appointed to fill the resulting vacancy shall be appointed for

the remainder of the term of the predecessor of the individual.

"(f) CHAIR.—The Director shall, from among the members of the Advisory Council appointed under subsection (c)(2), designate an individual to serve as the chair of the Advisory Council.

"(g) MEETINGS.—The Advisory Council shall meet not less than once during each discrete 4-month period and shall otherwise meet at the call of the Director or the chair.

"(h) COMPENSATION AND REIMBURSEMENT OF EXPENSES.—

"(1) APPOINTED MEMBERS.—Members of the Advisory Council appointed under subsection (c)(2) shall receive compensation for each day (including travel time) engaged in carrying out the duties of the Advisory Council unless declined by the member. Such compensation may not be in an amount in excess of the daily equivalent of the annual rate of basic pay prescribed for level IV of the Executive Schedule under section 5315 of title 5, United States Code, for each day during which such member is engaged in the performance of the duties of the Advisory Council.

"(2) EX OFFICIO MEMBERS.—Officials designated under subsection (c)(3) as ex officio members of the Advisory Council may not receive compensation

for service on the Advisory Council in addition to the compensation otherwise received for duties carried out as officers of the United States.

"(i) STAFF.—The Director shall provide to the Advisory Council such staff, information, and other assistance as may be necessary to carry out the duties of the Council.

"SEC. 922. PEER REVIEW WITH RESPECT TO GRANTS AND CONTRACTS.

"(a) REQUIREMENT OF REVIEW.—

"(1) IN GENERAL.—Appropriate technical and scientific peer review shall be conducted with respect to each application for a grant, cooperative agreement, or contract under this title.

"(2) REPORTS TO DIRECTOR.—Each peer review group to which an application is submitted pursuant to paragraph (1) shall report its finding and recommendations respecting the application to the Director in such form and in such manner as the Director shall require.

"(b) APPROVAL AS PRECONDITION OF AWARDS.—The Director may not approve an application described in subsection (a)(1) unless the application is recommended for approval by a peer review group established under subsection (c).

"(c) ESTABLISHMENT OF PEER REVIEW GROUPS.—

"(1) IN GENERAL.—The Director shall establish such technical and scientific peer review groups as may be necessary to carry out this section. Such groups shall be established without regard to the provisions of title 5, United States Code, that govern appointments in the competitive service, and without regard to the provisions of chapter 51, and subchapter III of chapter 53, of such title that relate to classification and pay rates under the General Schedule.

"(2) MEMBERSHIP.—The members of any peer review group established under this section shall be appointed from among individuals who by virtue of their training or experience are eminently qualified to carry out the duties of such peer review group. Officers and employees of the United States may not constitute more than 25 percent of the membership of any such group. Such officers and employees may not receive compensation for service on such groups in addition to the compensation otherwise received for these duties carried out as such officers and employees.

"(3) DURATION.—Notwithstanding section 14(a) of the Federal Advisory Committee Act, peer review groups established under this section may continue in existence until otherwise provided by law.

"(4) QUALIFICATIONS.—Members of any peer-review group shall, at a minimum, meet the following requirements:

"(A) Such members shall agree in writing to treat information received, pursuant to their work for the group, as confidential information, except that this subparagraph shall not apply to public records and public information.

"(B) Such members shall agree in writing to recuse themselves from participation in the peer-review of specific applications which present a potential personal conflict of interest or appearance of such conflict, including employment in a directly affected organization, stock ownership, or any financial or other arrangement that might introduce bias in the process of peer-review.

"(d) AUTHORITY FOR PROCEDURAL ADJUSTMENTS IN CERTAIN CASES.—In the case of applications for financial assistance whose direct costs will not exceed $100,000, the Director may make appropriate adjustments in the procedures otherwise established by the Director for the conduct of peer review under this section. Such adjustments may be made for the purpose of encouraging the entry of individuals into the field of research, for the purpose of encour-

aging clinical practice-oriented or provider-based research, and for such other purposes as the Director may determine to be appropriate.

"(e) REGULATIONS.—The Director shall issue regulations for the conduct of peer review under this section.

"SEC. 923. CERTAIN PROVISIONS WITH RESPECT TO DEVELOPMENT, COLLECTION, AND DISSEMINATION OF DATA.

"(a) STANDARDS WITH RESPECT TO UTILITY OF DATA.—

"(1) IN GENERAL.—To ensure the utility, accuracy, and sufficiency of data collected by or for the Agency for the purpose described in section 901(b), the Director shall establish standard methods for developing and collecting such data, taking into consideration—

"(A) other Federal health data collection standards; and

"(B) the differences between types of healthcare plans, delivery systems, healthcare providers, and provider arrangements.

"(2) RELATIONSHIP WITH OTHER DEPARTMENT PROGRAMS.—In any case where standards under paragraph (1) may affect the administration of other programs carried out by the Department of Health

and Human Services, including the programs under title XVIII, XIX or XXI of the Social Security Act, or may affect health information that is subject to a standard developed under part C of title XI of the Social Security Act, they shall be in the form of recommendations to the Secretary for such program.

"(b) STATISTICS AND ANALYSES.—The Director shall—

"(1) take appropriate action to ensure that statistics and analyses developed under this title are of high quality, timely, and duly comprehensive, and that the statistics are specific, standardized, and adequately analyzed and indexed; and

"(2) publish, make available, and disseminate such statistics and analyses on as wide a basis as is practicable.

"(c) AUTHORITY REGARDING CERTAIN REQUESTS.—Upon request of a public or private entity, the Director may conduct or support research or analyses otherwise authorized by this title pursuant to arrangements under which such entity will pay the cost of the services provided. Amounts received by the Director under such arrangements shall be available to the Director for obligation until expended.

"SEC. 924. DISSEMINATION OF INFORMATION.

"(a) IN GENERAL.—The Director shall—

"(1) without regard to section 501 of title 44, United States Code, promptly publish, make available, and otherwise disseminate, in a form understandable and on as broad a basis as practicable so as to maximize its use, the results of research, demonstration projects, and evaluations conducted or supported under this title;

"(2) ensure that information disseminated by the Agency is science-based and objective and undertakes consultation as necessary to assess the appropriateness and usefulness of the presentation of information that is targeted to specific audiences;

"(3) promptly make available to the public data developed in such research, demonstration projects, and evaluations;

"(4) provide, in collaboration with the National Library of Medicine where appropriate, indexing, abstracting, translating, publishing, and other services leading to a more effective and timely dissemination of information on research, demonstration projects, and evaluations with respect to healthcare to public and private entities and individuals engaged in the improvement of healthcare delivery and the general public, and undertake programs to develop new or

improved methods for making such information available; and

"(5) as appropriate, provide technical assistance to State and local government and health agencies and conduct liaison activities to such agencies to foster dissemination.

"(b) PROHIBITION AGAINST RESTRICTIONS.—Except as provided in subsection (c), the Director may not restrict the publication or dissemination of data from, or the results of, projects conducted or supported under this title.

"(c) LIMITATION ON USE OF CERTAIN INFORMATION.—No information, if an establishment or person supplying the information or described in it is identifiable, obtained in the course of activities undertaken or supported under this title may be used for any purpose other than the purpose for which it was supplied unless such establishment or person has consented (as determined under regulations of the Director) to its use for such other purpose. Such information may not be published or released in other form if the person who supplied the information or who is described in it is identifiable unless such person has consented (as determined under regulations of the Director) to its publication or release in other form.

"(d) PENALTY.—Any person who violates subsection (c) shall be subject to a civil monetary penalty of not more

than $10,000 for each such violation involved. Such penalty shall be imposed and collected in the same manner as civil money penalties under subsection (a) of section 1128A of the Social Security Act are imposed and collected.

"SEC. 925. ADDITIONAL PROVISIONS WITH RESPECT TO GRANTS AND CONTRACTS.

"(a) FINANCIAL CONFLICTS OF INTEREST.—With respect to projects for which awards of grants, cooperative agreements, or contracts are authorized to be made under this title, the Director shall by regulation define—

"(1) the specific circumstances that constitute financial interests in such projects that will, or may be reasonably expected to, create a bias in favor of obtaining results in the projects that are consistent with such interests; and

"(2) the actions that will be taken by the Director in response to any such interests identified by the Director.

"(b) REQUIREMENT OF APPLICATION.—The Director may not, with respect to any program under this title authorizing the provision of grants, cooperative agreements, or contracts, provide any such financial assistance unless an application for the assistance is submitted to the Secretary and the application is in such form, is made in such manner, and contains such agreements, assurances, and in-

formation as the Director determines to be necessary to carry out the program in involved.

"(c) PROVISION OF SUPPLIES AND SERVICES IN LIEU OF FUNDS.—

"(1) IN GENERAL.—Upon the request of an entity receiving a grant, cooperative agreement, or contract under this title, the Secretary may, subject to paragraph (2), provide supplies, equipment, and services for the purpose of aiding the entity in carrying out the project involved and, for such purpose, may detail to the entity any officer or employee of the Department of Health and Human Services.

"(2) CORRESPONDING REDUCTION IN FUNDS.—With respect to a request described in paragraph (1), the Secretary shall reduce the amount of the financial assistance involved by an amount equal to the costs of detailing personnel and the fair market value of any supplies, equipment, or services provided by the Director. The Secretary shall, for the payment of expenses incurred in complying with such request, expend the amounts withheld.

"(d) APPLICABILITY OF CERTAIN PROVISIONS WITH RESPECT TO CONTRACTS.—Contracts may be entered into under this part without regard to sections 3648 and 3709 of the Revised Statutes (31 U.S.C. 529; 41 U.S.C. 5).

"SEC. 926. CERTAIN ADMINISTRATIVE AUTHORITIES.

"(a) DEPUTY DIRECTOR AND OTHER OFFICERS AND EMPLOYEES.—

"(1) DEPUTY DIRECTOR.—The Director may appoint a deputy director for the Agency.

"(2) OTHER OFFICERS AND EMPLOYEES.—The Director may appoint and fix the compensation of such officers and employees as may be necessary to carry out this title. Except as otherwise provided by law, such officers and employees shall be appointed in accordance with the civil service laws and their compensation fixed in accordance with title 5, United States Code.

"(b) FACILITIES.—The Secretary, in carrying out this title—

"(1) may acquire, without regard to the Act of March 3, 1877 (40 U.S.C. 34), by lease or otherwise through the Director of General Services, buildings or portions of buildings in the District of Columbia or communities located adjacent to the District of Columbia for use for a period not to exceed 10 years; and

"(2) may acquire, construct, improve, repair, operate, and maintain laboratory, research, and other necessary facilities and equipment, and such other

real or personal property (including patents) as the Secretary deems necessary.

"(c) PROVISION OF FINANCIAL ASSISTANCE.—The Director, in carrying out this title, may make grants to public and nonprofit entities and individuals, and may enter into cooperative agreements or contracts with public and private entities and individuals.

"(d) UTILIZATION OF CERTAIN PERSONNEL AND RESOURCES.—

"(1) DEPARTMENT OF HEALTH AND HUMAN SERVICES.—The Director, in carrying out this title, may utilize personnel and equipment, facilities, and other physical resources of the Department of Health and Human Services, permit appropriate (as determined by the Secretary) entities and individuals to utilize the physical resources of such Department, and provide technical assistance and advice.

"(2) OTHER AGENCIES.—The Director, in carrying out this title, may use, with their consent, the services, equipment, personnel, information, and facilities of other Federal, State, or local public agencies, or of any foreign government, with or without reimbursement of such agencies.

"(e) CONSULTANTS.—The Secretary, in carrying out this title, may secure, from time to time and for such peri-

ods as the Director deems advisable but in accordance with section 3109 of title 5, United States Code, the assistance and advice of consultants from the United States or abroad.

"(f) EXPERTS.—

"(1) IN GENERAL.—The Secretary may, in carrying out this title, obtain the services of not more than 50 experts or consultants who have appropriate scientific or professional qualifications. Such experts or consultants shall be obtained in accordance with section 3109 of title 5, United States Code, except that the limitation in such section on the duration of service shall not apply.

"(2) TRAVEL EXPENSES.—

"(A) IN GENERAL.—Experts and consultants whose services are obtained under paragraph (1) shall be paid or reimbursed for their expenses associated with traveling to and from their assignment location in accordance with sections 5724, 5724a(a), 5724a(c), and 5726(C) of title 5, United States Code.

"(B) LIMITATION.—Expenses specified in subparagraph (A) may not be allowed in connection with the assignment of an expert or consultant whose services are obtained under paragraph (1) unless and until the expert agrees in writing

to complete the entire period of assignment, or 1 year, whichever is shorter, unless separated or reassigned for reasons that are beyond the control of the expert or consultant and that are acceptable to the Secretary. If the expert or consultant violates the agreement, the money spent by the United States for the expenses specified in subparagraph (A) is recoverable from the expert or consultant as a statutory obligation owed to the United States. The Secretary may waive in whole or in part a right of recovery under this subparagraph.

"(g) VOLUNTARY AND UNCOMPENSATED SERVICES.—The Director, in carrying out this title, may accept voluntary and uncompensated services.

"SEC. 927. FUNDING.

"(a) INTENT.—To ensure that the United States's investment in biomedical research is rapidly translated into improvements in the quality of patient care, there must be a corresponding investment in research on the most effective clinical and organizational strategies for use of these findings in daily practice. The authorization levels in subsection (b) provide for a proportionate increase in healthcare research as the United States investment in biomedical research increases.

"(b) AUTHORIZATION OF APPROPRIATIONS.—For the purpose of carrying out this title, there are authorized to be appropriated $250,000,000 for fiscal year 2000, and such sums as may be necessary for each of the fiscal years 2001 through 2006.

"(c) EVALUATIONS.—In addition to amounts available pursuant to subsection (b) for carrying out this title, there shall be made available for such purpose, from the amounts made available pursuant to section 241 (relating to evaluations), an amount equal to 40 percent of the maximum amount authorized in such section 241 to be made available for a fiscal year.

"SEC. 928. DEFINITIONS.

"In this title:

"(1) ADVISORY COUNCIL.—The term 'Advisory Council' means the Advisory Council on Healthcare Research and Quality established under section 921.

"(2) AGENCY.—The term 'Agency' means the Agency for Healthcare Research and Quality.

"(3) DIRECTOR.—The term 'Director' means the Director for the Agency for Healthcare Research and Quality.".

SEC. 403. REFERENCES.

Effective upon the date of enactment of this Act, any reference in law to the "Agency for Health Care Policy and

Research" shall be deemed to be a reference to the "Agency for Healthcare Research and Quality".

TITLE V—ENHANCED ACCESS TO HEALTH INSURANCE COVERAGE

SEC. 501. FULL DEDUCTION OF HEALTH INSURANCE COSTS FOR SELF-EMPLOYED INDIVIDUALS.

(a) IN GENERAL.—Section 162(l)(1) of the Internal Revenue Code of 1986 (relating to allowance of deductions) is amended to read as follows:

"(1) ALLOWANCE OF DEDUCTION.—In the case of an individual who is an employee within the meaning of section 401(c)(1), there shall be allowed as a deduction under this section an amount equal to the amount paid during the taxable year for insurance which constitutes medical care for the taxpayer, his spouse, and his dependents.".

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 1999.

SEC. 502. FULL AVAILABILITY OF MEDICAL SAVINGS ACCOUNTS.

(a) AVAILABILITY NOT LIMITED TO ACCOUNTS FOR EMPLOYEES OF SMALL EMPLOYERS AND SELF-EMPLOYED INDIVIDUALS.—

(1) IN GENERAL.—Section 220(c)(1)(A) of the Internal Revenue Code of 1986 (relating to eligible individual) is amended to read as follows:

"(A) IN GENERAL.—The term 'eligible individual' means, with respect to any month, any individual if—

"(i) such individual is covered under a high deductible health plan as of the 1st day of such month, and

"(ii) such individual is not, while covered under a high deductible health plan, covered under any health plan—

"(I) which is not a high deductible health plan, and

"(II) which provides coverage for any benefit which is covered under the high deductible health plan.".

(2) CONFORMING AMENDMENTS.—

(A) Section 220(c)(1) of such Code is amended by striking subparagraphs (C) and (D).

(B) Section 220(c) of such Code is amended by striking paragraph (4) (defining small employer) and by redesignating paragraph (5) as paragraph (4).

(C) Section 220(b) of such Code is amended by striking paragraph (4) (relating to deduction limited by compensation) and by redesignating paragraphs (5), (6), and (7) as paragraphs (4), (5), and (6), respectively.

(b) REMOVAL OF LIMITATION ON NUMBER OF TAXPAYERS HAVING MEDICAL SAVINGS ACCOUNTS.—

(1) IN GENERAL.—Section 220 of the Internal Revenue Code of 1986 (relating to medical savings accounts) is amended by striking subsections (i) and (j).

(2) MEDICARE+CHOICE.—Section 138 of such Code (relating to Medicare+Choice MSA) is amended by striking subsection (f).

(c) REDUCTION IN HIGH DEDUCTIBLE PLAN MINIMUM ANNUAL DEDUCTIBLE.—

(1) IN GENERAL.—Subparagraph (A) of section 220(c)(2) of such Code (defining high deductible health plan) is amended—

(A) by striking "$1,500" and inserting "$1,000", and

(B) by striking "$3,000" in clause (ii) and inserting "$2,000".

(2) CONFORMING AMENDMENT.—Subsection (g) of section 220 of such Code is amended—

(A) by striking "1998" and inserting "1999"; and

(B) by striking "1997" and inserting "1998".

(d) INCREASE IN CONTRIBUTION LIMIT TO 100 PERCENT OF ANNUAL DEDUCTIBLE.—

(1) IN GENERAL.—Section 220(b)(2) of the Internal Revenue Code of 1986 (relating to monthly limitation) is amended to read as follows:

"(2) MONTHLY LIMITATION.—The monthly limitation for any month is the amount equal to 1/12 of the annual deductible of the high deductible health plan of the individual.".

(2) CONFORMING AMENDMENT.—Section 220(d)(1)(A) of such Code is amended by striking "75 percent of".

(e) LIMITATION ON ADDITIONAL TAX ON DISTRIBUTIONS NOT USED FOR QUALIFIED MEDICAL EXPENSES.—Section 220(f)(4) of the Internal Revenue Code of 1986 (relating to additional tax on distributions not used for qualified medical expenses) is amended by adding at the end the following:

"(D) EXCEPTION IN CASE OF SUFFICIENT ACCOUNT BALANCE.—Subparagraph (A) shall not apply to any payment or distribution in

any taxable year, but only to the extent such payment or distribution does not reduce the fair market value of the assets of the medical savings account to an amount less than the annual deductible for the high deductible health plan of the account holder (determined as of January 1 of the calendar year in which the taxable year begins).".

(f) TREATMENT OF NETWORK-BASED MANAGED CARE PLANS.—Section 220(c)(2)(B) of the Internal Revenue Code of 1986 (relating to special rules for high deductible health plans) is amended by adding at the end the following:

"(iii) TREATMENT OF NETWORK-BASED MANAGED CARE PLANS.—A plan that provides health care services through a network of contracted or affiliated health care providers, if the benefits provided when services are obtained through network providers meet the requirements of subparagraph (A), shall not fail to be treated as a high deductible health plan by reason of providing benefits for services rendered by providers who are not members of the network, so long as the annual deductible and annual limit on out-of-pocket expenses applicable to services

received from non-network providers are not lower than those applicable to services received from the network providers.".

(g) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 1999.

SEC. 503. PERMITTING CONTRIBUTION TOWARDS MEDICAL SAVINGS ACCOUNT THROUGH FEDERAL EMPLOYEES HEALTH BENEFITS PROGRAM (FEHBP).

(a) AUTHORITY TO CONTRACT FOR CATASTROPHIC PLANS.—Section 8902 of title 5, United States Code, is amended by adding at the end the following:

"(p)(1) The Office shall contract under this chapter for a catastrophic plan with any qualified carrier that—

"(A) offers such a plan; and

"(B) as of the date of enactment of the Patients' Bill of Rights Plus Act, offers a health benefits plan under this chapter.

"(2) The Office may contract under this chapter for a catastrophic plan with any qualified carrier that—

"(A) offers such a plan; but

"(B) does not satisfy the requirement under paragraph (1)(B).".

(b) GOVERNMENT CONTRIBUTION TO MEDICAL SAVINGS ACCOUNT.—

(1) IN GENERAL.—Section 8906 of title 5, United States Code, is amended by adding at the end the following:

"(j)(1) In the case of an employee or annuitant who is enrolled in a catastrophic plan described by section 8903(5), there shall be a Government contribution under this subsection to a medical savings account established or maintained for the benefit of the individual. The contribution under this subsection shall be in addition to the Government contribution under subsection (b).

"(2) The amount of the Government contribution under this subsection with respect to an individual is equal to the amount by which—

"(A) the maximum contribution allowed under subsection (b)(1) with respect to any employee or annuitant, exceeds

"(B) the amount of the Government contribution actually made with respect to the individual under subsection (b) for coverage under the catastrophic plan.

"(3) The Government contributions under this subsection shall be paid into a medical savings account (designated by the individual involved) in a manner that is

specified by the Office and consistent with the timing of contributions under subsection (b).

"(4) Subsections (f) and (g) shall apply to contributions under this section in the same manner as they apply to contributions under subsection (b).

"(5) For the purpose of this subsection, the term 'medical savings account' has the meaning given such term by section 220(d) of the Internal Revenue Code of 1986.".

(2) ALLOWING PAYMENT OF FULL AMOUNT OF CHARGE FOR CATASTROPHIC PLAN.—Section 8906(b)(2) of such title is amended by inserting "(or 100 percent of the subscription charge in the case of a catastrophic plan)" after "75 percent of the subscription charge".

(c) OFFERING OF CATASTROPHIC PLANS.—

(1) IN GENERAL.—Section 8903 of title 5, United States Code, is amended by adding at the end the following:

"(5) CATASTROPHIC PLANS.—(A) One or more plans described in paragraph (1), (2), or (3), but which provide benefits of the types referred to by paragraph (5) of section 8904(a), instead of the types referred to in paragraphs (1), (2), and (3) of such section.

"(B) Nothing in this section shall be considered—

"(i) to prevent a carrier from simultaneously offering a plan described by subparagraph (A) and a plan described by paragraph (1) or (2);

"(ii) to require that a catastrophic plan offer two levels of benefits; or

"(iii) to allow, in any contract year, for—

"(I) more than one plan to be offered which satisfies both subparagraph (A) and paragraph (1) (subject to clause (ii)); and

"(II) more than one plan which satisfies both subparagraph (A) and paragraph (2) (subject to clause (ii)).".

(2) TYPES OF BENEFITS.—Section 8904(a) of such title is amended by inserting after paragraph (4) the following new paragraph:

"(5) CATASTROPHIC PLANS.—Benefits of the types named under paragraph (1) or (2) of this subsection or both, except that the plan shall meet the annual deductible and annual out-of-pocket expenses requirements under section 220(c)(2) of the Internal Revenue Code of 1986.".

(3) DETERMINING LEVEL OF GOVERNMENT CONTRIBUTIONS.—Section 8906(b) of such title is amended by adding at the end the following: "Subscription charges for medical savings accounts shall be deemed to be the amount of Government contributions made under subsection (j)(2).".

(d) CONFORMING AMENDMENTS.—

(1) ADDITIONAL HEALTH BENEFITS PLANS.—Section 8903a of title 5, United States Code, is amended by redesignating subsection (d) as subsection (e) and by inserting after subsection (c) the following:

"(d) The plans under this section may include one or more plans, otherwise allowable under this section, that satisfy the requirements of clauses (i) and (ii) of section 8903(5)(A).".

(2) REFERENCE.—Section 8909(d) of title 5, United States Code, is amended by striking "8903a(d)" and inserting "8903a(e)".

(e) REFERENCES.—Section 8903 of title 5, United States Code, is amended by adding at the end (as a flush left sentence) the following:

"The Office shall prescribe regulations under which the requirements of section 8902(c), 8902(n), 8909(e), and any other provision of this chapter that applies with respect to a plan described by paragraph (1), (2), (3), or (4) of this

section shall apply with respect to the corresponding plan under paragraph (5) of this section. Similar regulations shall be prescribed with respect to any plan under section 8903a(d).".

(f) EFFECTIVE DATE.—The amendments made by this section shall apply to contract terms beginning on or after January 1, 2000.

SEC. 504. CARRYOVER OF UNUSED BENEFITS FROM CAFETERIA PLANS, FLEXIBLE SPENDING ARRANGEMENTS, AND HEALTH FLEXIBLE SPENDING ACCOUNTS.

(a) IN GENERAL.—Section 125 of the Internal Revenue Code of 1986 (relating to cafeteria plans) is amended by redesignating subsections (h) and (i) as subsections (i) and (j) and by inserting after subsection (g) the following new subsection:

"(h) ALLOWANCE OF CARRYOVERS OF UNUSED BENEFITS TO LATER TAXABLE YEARS.—

"(1) IN GENERAL.—For purposes of this title—

"(A) notwithstanding subsection (d)(2), a plan or other arrangement shall not fail to be treated as a cafeteria plan or flexible spending or similar arrangement, and

"(B) no amount shall be required to be included in gross income by reason of this section or any other provision of this chapter,

solely because under such plan or other arrangement any nontaxable benefit which is unused as of the close of a taxable year may be carried forward to 1 or more succeeding taxable years.

"(2) LIMITATION.—Paragraph (1) shall not apply to amounts carried from a plan to the extent such amounts exceed $500 (applied on an annual basis). For purposes of this paragraph, all plans and arrangements maintained by an employer or any related person shall be treated as 1 plan.

"(3) ALLOWANCE OF ROLLOVER.—

"(A) IN GENERAL.—In the case of any unused benefit described in paragraph (1) which consists of amounts in a health flexible spending account or dependent care flexible spending account, the plan or arrangement shall provide that a participant may elect, in lieu of such carryover, to have such amounts distributed to the participant.

"(B) AMOUNTS NOT INCLUDED IN INCOME.—Any distribution under subparagraph (A) shall not be included in gross income to the

extent that such amount is transferred in a trustee-to-trustee transfer, or is contributed within 60 days of the date of the distribution, to—

"(i) a qualified cash or deferred arrangement described in section 401(k),

"(ii) a plan under which amounts are contributed by an individual's employer for an annuity contract described in section 403(b),

"(iii) an eligible deferred compensation plan described in section 457, or

"(iv) a medical savings account (within the meaning of section 220).

Any amount rolled over under this subparagraph shall be treated as a rollover contribution for the taxable year from which the unused amount would otherwise be carried.

"(C) TREATMENT OF ROLLOVER.—Any amount rolled over under subparagraph (B) shall be treated as an eligible rollover under section 220, 401(k), 403(b), or 457, whichever is applicable, and shall be taken into account in applying any limitation (or participation requirement) on employer or employee contributions

under such section or any other provision of this chapter for the taxable year of the rollover.

"(4) COST-OF-LIVING ADJUSTMENT.—In the case of any taxable year beginning in a calendar year after 1999, the $500 amount under paragraph (2) shall be adjusted at the same time and in the same manner as under section 415(d)(2), except that the base period taken into account shall be the calendar quarter beginning October 1, 1998, and any increase which is not a multiple of $50 shall be rounded to the next lowest multiple of $50.

"(5) APPLICABILITY.—This subsection shall apply to taxable years beginning after December 31, 1999.".

(b) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 1999.

TITLE VI—PROVISIONS RELATING TO LONG-TERM CARE INSURANCE

SEC. 601. INCLUSION OF QUALIFIED LONG-TERM CARE INSURANCE CONTRACTS IN CAFETERIA PLANS, FLEXIBLE SPENDING ARRANGEMENTS, AND HEALTH FLEXIBLE SPENDING ACCOUNTS.

(a) IN GENERAL.—Section 125(f) of the Internal Revenue Code of 1986 (defining qualified benefits) is amended by striking the last sentence and inserting the following: "Such term includes any qualified long-term care insurance contract.".

(b) EFFECTIVE DATE.—The amendment made by this section shall apply to taxable years beginning after December 31, 1999.

SEC. 602. DEDUCTION FOR PREMIUMS FOR LONG-TERM CARE INSURANCE.

(a) IN GENERAL.—Part VII of subchapter B of chapter 1 of the Internal Revenue Code of 1986 (relating to additional itemized deductions) is amended by redesignating section 222 as section 223 and by inserting after section 221 the following:

"SEC. 222. PREMIUMS FOR LONG-TERM CARE INSURANCE.

"(a) IN GENERAL.—In the case of an eligible individual, there shall be allowed as a deduction an amount

equal to 100 percent of the amount paid during the taxable year for any coverage for qualified long-term care services (as defined in section 7702B(c)) or any qualified long-term care insurance contract (as defined in section 7702B(b)) which constitutes medical care for the taxpayer, his spouse, and dependents.

"(b) LIMITATIONS.—

"(1) DEDUCTION NOT AVAILABLE TO INDIVIDUALS ELIGIBLE FOR EMPLOYER-SUBSIDIZED COVERAGE.—

"(A) IN GENERAL.—Except as provided in subparagraph (B), subsection (a) shall not apply to any taxpayer for any calendar month for which the taxpayer is eligible to participate in any plan which includes coverage for qualified long-term care services (as so defined) or is a qualified long-term care insurance contract (as so defined) maintained by any employer (or former employer) of the taxpayer or of the spouse of the taxpayer.

"(B) CONTINUATION COVERAGE.—Coverage shall not be treated as subsidized for purposes of this paragraph if—

"(i) such coverage is continuation coverage (within the meaning of section

4980B(f)) required to be provided by the employer, and

"(ii) the taxpayer or the taxpayer's spouse is required to pay a premium for such coverage in an amount not less than 100 percent of the applicable premium (within the meaning of section 4980B(f)(4)) for the period of such coverage.

"(2) LIMITATION ON LONG-TERM CARE PREMIUMS.—In the case of a qualified long-term care insurance contract (as so defined), only eligible long-term care premiums (as defined in section 213(d)(10)) shall be taken into account under subsection (a)(2).

"(c) SPECIAL RULES.—For purposes of this section—

"(1) COORDINATION WITH MEDICAL DEDUCTION, ETC.—Any amount paid by a taxpayer for insurance to which subsection (a) applies shall not be taken into account in computing the amount allowable to the taxpayer as a deduction under section 213(a).

"(2) DEDUCTION NOT ALLOWED FOR SELF-EMPLOYMENT TAX PURPOSES.—The deduction allowable by reason of this section shall not be taken into account in determining an individual's net earnings

from self-employment (within the meaning of section 1402(a)) for purposes of chapter 2.".

(b) CONFORMING AMENDMENTS.—

(1) Subsection (a) of section 62 of the Internal Revenue Code of 1986 is amended by inserting after paragraph (17) the following:

"(18) LONG-TERM CARE INSURANCE COSTS OF CERTAIN INDIVIDUALS.—The deduction allowed by section 222.".

(2) The table of sections for part VII of subchapter B of chapter 1 of such Code is amended by striking the last item and inserting the following:

"Sec. 222. Premiums for long-term care insurance.
"Sec. 223. Cross reference.".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to taxable years beginning after December 31, 1999.

SEC. 603. STUDY OF LONG-TERM CARE NEEDS IN THE 21ST CENTURY.

(a) IN GENERAL.—The Secretary of Health and Human Services (referred to in this section as the "Secretary") shall provide, in accordance with this section, for a study in order to determine—

(1) future demand for long-term health care services (including institutional and home and commu-

nity-based services) in the United States in order to meet the needs in the 21st century; and

(2) long-term options to finance the provision of such services.

(b) DETAILS.—The study conducted under subsection (a) shall include the following:

(1) An identification of the relevant demographic characteristics affecting demand for long-term health care services, at least through the year 2030.

(2) The viability and capacity of community-based and other long-term health care services under different federal programs, including through the medicare and medicaid programs, grants to States, housing services, and changes in tax policy.

(3) How to improve the quality of long-term health care services.

(4) The integration of long-term health care services for individuals between different classes of health care providers (such as hospitals, nursing facilities, and home care agencies) and different Federal programs (such as the medicare and medicaid programs).

(5) The possibility of expanding private sector initiatives, including long-term care insurance, to meet the need to finance such services.

(6) An examination of the effect of enactment of the Health Insurance Portability and Accountability Act of 1996 on the provision and financing of long-term health care services, including on portability and affordability of private long-term care insurance, the impact of insurance options on low-income older Americans, and the options for eligibility to improve access to such insurance.

(7) The financial impact of the provision of long-term health care services on caregivers and other family members.

(c) REPORT AND RECOMMENDATIONS.—

(1) IN GENERAL.—Not later than 1 year after the date of the enactment of this Act, the Secretary shall provide for a report on the study under this section.

(2) RECOMMENDATIONS.—The report under paragraph (1) shall include findings and recommendations regarding each of the following:

(A) The most effective and efficient manner that the Federal government may use its resources to educate the public on planning for needs for long-term health care services.

(B) The public, private, and joint public-private strategies for meeting identified needs for long-term health care services.

(C) The role of States and local communities in the financing of long-term health care services.

(3) INCLUSION OF COST ESTIMATES.—The report under paragraph (1) shall include cost estimates of the various options for which recommendations are made.

(d) CONDUCT OF STUDY.—

(1) USE OF INSTITUTE OF MEDICINE.—The Secretary of Health and Human Services shall seek to enter into an appropriate arrangement with the Institute of Medicine of the National Academy of Sciences to conduct the study under this section. If such an arrangement cannot be made, the Secretary may provide for the conduct of the study by any other qualified non-governmental entity.

(2) CONSULTATION.—The study should be conducted under this section in consultation with experts from a wide-range of groups from the public and private sectors.

TITLE VII—INDIVIDUAL RETIREMENT PLANS

SEC. 701. MODIFICATION OF INCOME LIMITS ON CONTRIBUTIONS AND ROLLOVERS TO ROTH IRAS.

(a) INCREASE IN AGI LIMIT FOR ROLLOVER CONTRIBUTIONS.—Clause (i) of section 408A(c)(3)(A) of the Internal Revenue Code of 1986 (relating to rollover from IRA), as redesignated by subsection (a), is amended by striking "$100,000" and inserting "$1,000,000".

(b) CONFORMING AMENDMENTS.—

(1)(A) Subparagraph (B) of section 408A(c)(3) of the Internal Revenue Code of 1986, as redesignated by subsection (a), is amended to read as follows:

"(B) DEFINITION OF ADJUSTED GROSS INCOME.—For purposes of subparagraph (A), adjusted gross income shall be determined—

"(i) after application of sections 86 and 469, and

"(ii) without regard to sections 135, 137, 221, and 911, the deduction allowable under section 219, or any amount included in gross income under subsection (d)(3).".

(B) EFFECTIVE DATE.—The amendment made by this paragraph shall apply to taxable years beginning after December 31, 1999.

(2)(A) Subparagraph (B) of section 408A(c)(3) of such Code, as amended by paragraph (1), is amended to read as follows:

"(B) DEFINITION OF ADJUSTED GROSS INCOME.—For purposes of subparagraph (A), adjusted gross income shall be determined—

"(i) after application of sections 86 and 469, and

"(ii) without regard to sections 135, 137, 221, and 911, the deduction allowable under section 219, or any amount included in gross income under subsection (d)(3) or by reason of a required distribution under a provision described in paragraph (5).".

(B) EFFECTIVE DATE.—The amendment made by this paragraph shall apply to taxable years beginning after December 31, 2004.

(c) EFFECTIVE DATE.—Except as otherwise provided in this section, the amendments made by this section shall apply to taxable years beginning after December 31, 1999.

TITLE VIII—REVENUE PROVISIONS

SEC. 801. MODIFICATION TO FOREIGN TAX CREDIT CARRYBACK AND CARRYOVER PERIODS.

(a) IN GENERAL.—Section 904(c) of the Internal Revenue Code of 1986 (relating to limitation on credit) is amended—

(1) by striking "in the second preceding taxable year,", and

(2) by striking "or fifth" and inserting "fifth, sixth, or seventh".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to credits arising in taxable years beginning after December 31, 2001.

SEC. 802. LIMITATION ON USE OF NON-ACCRUAL EXPERIENCE METHOD OF ACCOUNTING.

(a) IN GENERAL.—Section 448(d)(5) of the Internal Revenue Code of 1986 (relating to special rule for services) is amended—

(1) by inserting "in fields described in paragraph (2)(A)" after "services by such person", and

(2) by inserting "CERTAIN PERSONAL" before "SERVICES" in the heading.

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—The amendments made by this section shall apply to taxable years ending after the date of the enactment of this Act.

(2) CHANGE IN METHOD OF ACCOUNTING.—In the case of any taxpayer required by the amendments made by this section to change its method of accounting for its first taxable year ending after the date of the enactment of this Act—

(A) such change shall be treated as initiated by the taxpayer,

(B) such change shall be treated as made with the consent of the Secretary of the Treasury, and

(C) the net amount of the adjustments required to be taken into account by the taxpayer under section 481 of the Internal Revenue Code of 1986 shall be taken into account over a period (not greater than 4 taxable years) beginning with such first taxable year.

SEC. 803. RETURNS RELATING TO CANCELLATIONS OF INDEBTEDNESS BY ORGANIZATIONS LENDING MONEY.

(a) IN GENERAL.—Paragraph (2) of section 6050P(c) of the Internal Revenue Code of 1986 (relating to definitions and special rules) is amended by striking "and" at the end

of subparagraph (B), by striking the period at the end of subparagraph (C) and inserting ", and", and by inserting after subparagraph (C) the following new subparagraph:

"(D) any organization a significant trade or business of which is the lending of money.".

(b) EFFECTIVE DATE.—The amendment made by subsection (a) shall apply to discharges of indebtedness after December 31, 1999.

SEC. 804. EXTENSION OF INTERNAL REVENUE SERVICE USER FEES.

(a) IN GENERAL.—Chapter 77 of the Internal Revenue Code of 1986 (relating to miscellaneous provisions) is amended by adding at the end the following new section:

"SEC. 7527. INTERNAL REVENUE SERVICE USER FEES.

"(a) GENERAL RULE.—The Secretary shall establish a program requiring the payment of user fees for—

"(1) requests to the Internal Revenue Service for ruling letters, opinion letters, and determination letters, and

"(2) other similar requests.

"(b) PROGRAM CRITERIA.—

"(1) IN GENERAL.—The fees charged under the program required by subsection (a)—

"(A) shall vary according to categories (or subcategories) established by the Secretary,

"(B) shall be determined after taking into account the average time for (and difficulty of) complying with requests in each category (and subcategory), and

"(C) shall be payable in advance.

"(2) EXEMPTIONS, ETC.—The Secretary shall provide for such exemptions (and reduced fees) under such program as the Secretary determines to be appropriate.

"(3) AVERAGE FEE REQUIREMENT.—The average fee charged under the program required by subsection (a) shall not be less than the amount determined under the following table:

"Category	***Average Fee***
Employee plan ruling and opinion	*$250*
Exempt organization ruling	*$350*
Employee plan determination	*$300*
Exempt organization determination	*$275*
Chief counsel ruling	*$200.*

"(c) TERMINATION.—No fee shall be imposed under this section with respect to requests made after September 30, 2009.".

(b) CONFORMING AMENDMENTS.—

(1) The table of sections for chapter 77 of the Internal Revenue Code of 1986 is amended by adding at the end the following new item:

"Sec. 7527. Internal Revenue Service user fees.".

(2) Section 10511 of the Revenue Act of 1987 is repealed.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to requests made after the date of the enactment of this Act.

SEC. 805. PROPERTY SUBJECT TO A LIABILITY TREATED IN SAME MANNER AS ASSUMPTION OF LIABILITY.

(a) REPEAL OF PROPERTY SUBJECT TO A LIABILITY TEST.—

(1) SECTION 357.—Section 357(a)(2) of the Internal Revenue Code of 1986 (relating to assumption of liability) is amended by striking ", or acquires from the taxpayer property subject to a liability".

(2) SECTION 358.—Section 358(d)(1) of such Code (relating to assumption of liability) is amended by striking "or acquired from the taxpayer property subject to a liability".

(3) SECTION 368.—

(A) Section 368(a)(1)(C) of such Code is amended by striking ", or the fact that property acquired is subject to a liability,".

(B) The last sentence of section 368(a)(2)(B) of such Code is amended by striking ", and the amount of any liability to which

any property acquired from the acquiring corporation is subject,".

(b) CLARIFICATION OF ASSUMPTION OF LIABILITY.—

(1) IN GENERAL.—Section 357 of the Internal Revenue Code of 1986 is amended by adding at the end the following new subsection:

"(d) DETERMINATION OF AMOUNT OF LIABILITY ASSUMED.—

"(1) IN GENERAL.—For purposes of this section, section 358(d), section 362(d), section 368(a)(1)(C), and section 368(a)(2)(B), except as provided in regulations—

"(A) a recourse liability (or portion thereof) shall be treated as having been assumed if, as determined on the basis of all facts and circumstances, the transferee has agreed to, and is expected to, satisfy such liability (or portion), whether or not the transferor has been relieved of such liability, and

"(B) except to the extent provided in paragraph (2), a nonrecourse liability shall be treated as having been assumed by the transferee of any asset subject to such liability.

"(2) EXCEPTION FOR NONRECOURSE LIABILITY.—The amount of the nonrecourse liability treated

as described in paragraph (1)(B) shall be reduced by the lesser of—

"(A) the amount of such liability which an owner of other assets not transferred to the transferee and also subject to such liability has agreed with the transferee to, and is expected to, satisfy, or

"(B) the fair market value of such other assets (determined without regard to section 7701(g)).

"(3) REGULATIONS.—The Secretary shall prescribe such regulations as may be necessary to carry out the purposes of this subsection and section 362(d). The Secretary may also prescribe regulations which provide that the manner in which a liability is treated as assumed under this subsection is applied, where appropriate, elsewhere in this title.".

(2) LIMITATION ON BASIS INCREASE ATTRIBUTABLE TO ASSUMPTION OF LIABILITY.—Section 362 of such Code is amended by adding at the end the following new subsection:

"(d) LIMITATION ON BASIS INCREASE ATTRIBUTABLE TO ASSUMPTION OF LIABILITY.—

"(1) IN GENERAL.—In no event shall the basis of any property be increased under subsection (a) or (b)

above the fair market value of such property (determined without regard to section 7701(g)) by reason of any gain recognized to the transferor as a result of the assumption of a liability.

"(2) TREATMENT OF GAIN NOT SUBJECT TO TAX.—Except as provided in regulations, if—

"(A) gain is recognized to the transferor as a result of an assumption of a nonrecourse liability by a transferee which is also secured by assets not transferred to such transferee, and

"(B) no person is subject to tax under this title on such gain,

then, for purposes of determining basis under subsections (a) and (b), the amount of gain recognized by the transferor as a result of the assumption of the liability shall be determined as if the liability assumed by the transferee equaled such transferee's ratable portion of such liability determined on the basis of the relative fair market values (determined without regard to section 7701(g)) of all of the assets subject to such liability.".

(c) APPLICATION TO PROVISIONS OTHER THAN SUBCHAPTER C.—

(1) SECTION 584.—Section 584(h)(3) of the Internal Revenue Code of 1986 is amended—

(A) by striking ", and the fact that any property transferred by the common trust fund is subject to a liability," in subparagraph (A), and

(B) by striking clause (ii) of subparagraph (B) and inserting:

"(ii) ASSUMED LIABILITIES.—For purposes of clause (i), the term 'assumed liabilities' means any liability of the common trust fund assumed by any regulated investment company in connection with the transfer referred to in paragraph (1)(A).

"(C) ASSUMPTION.—For purposes of this paragraph, in determining the amount of any liability assumed, the rules of section 357(d) shall apply.".

(2) SECTION 1031.—The last sentence of section 1031(d) of such Code is amended—

(A) by striking "assumed a liability of the taxpayer or acquired from the taxpayer property subject to a liability" and inserting "assumed (as determined under section 357(d)) a liability of the taxpayer", and

(B) by striking "or acquisition (in the amount of the liability)".

(d) CONFORMING AMENDMENTS.—

(1) Section 351(h)(1) of the Internal Revenue Code of 1986 is amended by striking ", or acquires property subject to a liability,".

(2) Section 357 of such Code is amended by striking "or acquisition" each place it appears in subsection (a) or (b).

(3) Section 357(b)(1) of such Code is amended by striking "or acquired".

(4) Section 357(c)(1) of such Code is amended by striking ", plus the amount of the liabilities to which the property is subject,".

(5) Section 357(c)(3) of such Code is amended by striking "or to which the property transferred is subject".

(6) Section 358(d)(1) of such Code is amended by striking "or acquisition (in the amount of the liability)".

(e) EFFECTIVE DATE.—The amendments made by this section shall apply to transfers after October 19, 1998.

SEC. 806. CHARITABLE SPLIT-DOLLAR LIFE INSURANCE, ANNUITY, AND ENDOWMENT CONTRACTS.

(a) IN GENERAL.—Subsection (f) of section 170 of the Internal Revenue Code of 1986 (relating to disallowance of deduction in certain cases and special rules) is amended by adding at the end the following new paragraph:

"(10) SPLIT-DOLLAR LIFE INSURANCE, ANNUITY, AND ENDOWMENT CONTRACTS.—

"(A) IN GENERAL.—Nothing in this section or in section 545(b)(2), 556(b)(2), 642(c), 2055, 2106(a)(2), or 2522 shall be construed to allow a deduction, and no deduction shall be allowed, for any transfer to or for the use of an organization described in subsection (c) if in connection with such transfer—

"(i) the organization directly or indirectly pays, or has previously paid, any premium on any personal benefit contract with respect to the transferor, or

"(ii) there is an understanding or expectation that any person will directly or indirectly pay any premium on any personal benefit contract with respect to the transferor.

"(B) PERSONAL BENEFIT CONTRACT.—For purposes of subparagraph (A), the term 'personal benefit contract' means, with respect to the transferor, any life insurance, annuity, or endowment contract if any direct or indirect beneficiary under such contract is the transferor, any member of the transferor's family, or any other

person (other than an organization described in subsection (c)) designated by the transferor.

"(C) APPLICATION TO CHARITABLE REMAINDER TRUSTS.—In the case of a transfer to a trust referred to in subparagraph (E), references in subparagraphs (A) and (F) to an organization described in subsection (c) shall be treated as a reference to such trust.

"(D) EXCEPTION FOR CERTAIN ANNUITY CONTRACTS.—If, in connection with a transfer to or for the use of an organization described in subsection (c), such organization incurs an obligation to pay a charitable gift annuity (as defined in section 501(m)) and such organization purchases any annuity contract to fund such obligation, persons receiving payments under the charitable gift annuity shall not be treated for purposes of subparagraph (B) as indirect beneficiaries under such contract if—

"(i) such organization possesses all of the incidents of ownership under such contract,

"(ii) such organization is entitled to all the payments under such contract, and

"(iii) the timing and amount of payments under such contract are substantially the same as the timing and amount of payments to each such person under such obligation (as such obligation is in effect at the time of such transfer).

"(E) EXCEPTION FOR CERTAIN CONTRACTS HELD BY CHARITABLE REMAINDER TRUSTS.—A person shall not be treated for purposes of subparagraph (B) as an indirect beneficiary under any life insurance, annuity, or endowment contract held by a charitable remainder annuity trust or a charitable remainder unitrust (as defined in section 664(d)) solely by reason of being entitled to any payment referred to in paragraph (1)(A) or (2)(A) of section 664(d) if—

"(i) such trust possesses all of the incidents of ownership under such contract, and

"(ii) such trust is entitled to all the payments under such contract.

"(F) EXCISE TAX ON PREMIUMS PAID.—

"(i) IN GENERAL.—There is hereby imposed on any organization described in subsection (c) an excise tax equal to the premiums paid by such organization on any

life insurance, annuity, or endowment contract if the payment of premiums on such contract is in connection with a transfer for which a deduction is not allowable under subparagraph (A), determined without regard to when such transfer is made.

"(ii) PAYMENTS BY OTHER PERSONS.—For purposes of clause (i), payments made by any other person pursuant to an understanding or expectation referred to in subparagraph (A) shall be treated as made by the organization.

"(iii) REPORTING.—Any organization on which tax is imposed by clause (i) with respect to any premium shall file an annual return which includes—

"(I) the amount of such premiums paid during the year and the name and TIN of each beneficiary under the contract to which the premium relates, and

"(II) such other information as the Secretary may require.

The penalties applicable to returns required under section 6033 shall apply to returns

required under this clause. Returns required under this clause shall be furnished at such time and in such manner as the Secretary shall by forms or regulations require.

"(iv) CERTAIN RULES TO APPLY.—The tax imposed by this subparagraph shall be treated as imposed by chapter 42 for purposes of this title other than subchapter B of chapter 42.

"(G) SPECIAL RULE WHERE STATE REQUIRES SPECIFICATION OF CHARITABLE GIFT ANNUITANT IN CONTRACT.—In the case of an obligation to pay a charitable gift annuity referred to in subparagraph (D) which is entered into under the laws of a State which requires, in order for the charitable gift annuity to be exempt from insurance regulation by such State, that each beneficiary under the charitable gift annuity be named as a beneficiary under an annuity contract issued by an insurance company authorized to transact business in such State, the requirements of clauses (i) and (ii) of subparagraph (D) shall be treated as met if—

"(i) such State law requirement was in effect on February 8, 1999,

"(ii) each such beneficiary under the charitable gift annuity is a bona fide resident of such State at the time the obligation to pay a charitable gift annuity is entered into, and

"(iii) the only persons entitled to payments under such contract are persons entitled to payments as beneficiaries under such obligation on the date such obligation is entered into.

"(H) REGULATIONS.—The Secretary shall prescribe such regulations as may be necessary or appropriate to carry out the purposes of this paragraph, including regulations to prevent the avoidance of such purposes.".

(b) EFFECTIVE DATE.—

(1) IN GENERAL.—Except as otherwise provided in this section, the amendment made by this section shall apply to transfers made after February 8, 1999.

(2) EXCISE TAX.—Except as provided in paragraph (3) of this subsection, section 170(f)(10)(F) of the Internal Revenue Code of 1986 (as added by this section) shall apply to premiums paid after the date of the enactment of this Act.

(3) REPORTING.—Clause (iii) of such section 170(f)(10)(F) shall apply to premiums paid after February 8, 1999 (determined as if the tax imposed by such section applies to premiums paid after such date).

SEC. 807. TRANSFER OF EXCESS DEFINED BENEFIT PLAN ASSETS FOR RETIREE HEALTH BENEFITS.

(a) EXTENSION.—

(1) IN GENERAL.—Section 420(b)(5) of the Internal Revenue Code of 1986 (relating to expiration) is amended by striking "in any taxable year beginning after December 31, 2000" and inserting "made after September 30, 2009".

(2) CONFORMING AMENDMENTS.—

(A) Section 101(e)(3) of the Employee Retirement Income Security Act of 1974 (29 U.S.C. 1021(e)(3)) is amended by striking "1995" and inserting "2001".

(B) Section 403(c)(1) of such Act (29 U.S.C. 1103(c)(1)) is amended by striking "1995" and inserting "2001".

(C) Paragraph (13) of section 408(b) of such Act (29 U.S.C. 1108(b)(13)) is amended—

(i) by striking "in a taxable year beginning before January 1, 2001" and inserting "made before October 1, 2009", and

(ii) by striking "1995" and inserting "2001".

(b) APPLICATION OF MINIMUM COST REQUIREMENTS.—

(1) IN GENERAL.—Section 420(c)(3) of the Internal Revenue Code of 1986 is amended to read as follows:

"(3) MINIMUM COST REQUIREMENTS.—

"(A) IN GENERAL.—The requirements of this paragraph are met if each group health plan or arrangement under which applicable health benefits are provided provides that the applicable employer cost for each taxable year during the cost maintenance period shall not be less than the higher of the applicable employer costs for each of the 2 taxable years immediately preceding the taxable year of the qualified transfer.

"(B) APPLICABLE EMPLOYER COST.—For purposes of this paragraph, the term 'applicable employer cost' means, with respect to any taxable year, the amount determined by dividing—

"(i) the qualified current retiree health liabilities of the employer for such taxable year determined—

"(I) without regard to any reduction under subsection (e)(1)(B), and

"(II) in the case of a taxable year in which there was no qualified transfer, in the same manner as if there had been such a transfer at the end of the taxable year, by

"(ii) the number of individuals to whom coverage for applicable health benefits was provided during such taxable year.

"(C) ELECTION TO COMPUTE COST SEPARATELY.—An employer may elect to have this paragraph applied separately with respect to individuals eligible for benefits under title XVIII of the Social Security Act at any time during the taxable year and with respect to individuals not so eligible.

"(D) COST MAINTENANCE PERIOD.—For purposes of this paragraph, the term 'cost maintenance period' means the period of 5 taxable years beginning with the taxable year in which the qualified transfer occurs. If a taxable year is

in 2 or more overlapping cost maintenance periods, this paragraph shall be applied by taking into account the highest applicable employer cost required to be provided under subparagraph (A) for such taxable year.''.

(2) CONFORMING AMENDMENTS.—

(A) Section 420(b)(1)(C)(iii) of such Code is amended by striking ''benefits'' and inserting ''cost''.

(B) Section 420(e)(1)(D) of such Code is amended by striking ''and shall not be subject to the minimum benefit requirements of subsection (c)(3)'' and inserting ''or in calculating applicable employer cost under subsection (c)(3)(B)''.

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to qualified transfers occurring after December 31, 2000, and before October 1, 2009.

SEC. 808. LIMITATIONS ON WELFARE BENEFIT FUNDS OF 10 OR MORE EMPLOYER PLANS.

(a) BENEFITS TO WHICH EXCEPTION APPLIES.—Section 419A(f)(6)(A) of the Internal Revenue Code of 1986 (relating to exception for 10 or more employer plans) is amended to read as follows:

''(A) IN GENERAL.—This subpart shall not apply to a welfare benefit fund which is part of

a 10 or more employer plan if the only benefits provided through the fund are 1 or more of the following:

"(i) Medical benefits.

"(ii) Disability benefits.

"(iii) Group term life insurance benefits which do not provide for any cash surrender value or other money that can be paid, assigned, borrowed, or pledged for collateral for a loan.

The preceding sentence shall not apply to any plan which maintains experience-rating arrangements with respect to individual employers.".

(b) LIMITATION ON USE OF AMOUNTS FOR OTHER PURPOSES.—Section 4976(b) of the Internal Revenue Code of 1986 (defining disqualified benefit) is amended by adding at the end the following new paragraph:

"(5) SPECIAL RULE FOR 10 OR MORE EMPLOYER PLANS EXEMPTED FROM PREFUNDING LIMITS.—For purposes of paragraph (1)(C), if—

"(A) subpart D of part I of subchapter D of chapter 1 does not apply by reason of section 419A(f)(6) to contributions to provide 1 or more welfare benefits through a welfare benefit fund under a 10 or more employer plan, and

"(B) any portion of the welfare benefit fund attributable to such contributions is used for a purpose other than that for which the contributions were made,

then such portion shall be treated as reverting to the benefit of the employers maintaining the fund.".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to contributions paid or accrued after the date of the enactment of this Act, in taxable years ending after such date.

SEC. 809. MODIFICATION OF INSTALLMENT METHOD AND REPEAL OF INSTALLMENT METHOD FOR ACCRUAL METHOD TAXPAYERS.

(a) REPEAL OF INSTALLMENT METHOD FOR ACCRUAL BASIS TAXPAYERS.—

(1) IN GENERAL.—Subsection (a) of section 453 of the Internal Revenue Code of 1986 (relating to installment method) is amended to read as follows:

"(a) USE OF INSTALLMENT METHOD.—

"(1) IN GENERAL.—Except as otherwise provided in this section, income from an installment sale shall be taken into account for purposes of this title under the installment method.

"(2) ACCRUAL METHOD TAXPAYER.—The installment method shall not apply to income from an in-

stallment sale if such income would be reported under an accrual method of accounting without regard to this section. The preceding sentence shall not apply to a disposition described in subparagraph (A) or (B) of subsection (l)(2).".

(2) CONFORMING AMENDMENTS.—Sections 453(d)(1), 453(i)(1), and 453(k) of such Code are each amended by striking "(a)" each place it appears and inserting "(a)(1)".

(b) MODIFICATION OF PLEDGE RULES.—Paragraph (4) of section 453A(d) of the Internal Revenue Code of 1986 (relating to pledges, etc., of installment obligations) is amended by adding at the end the following: "A payment shall be treated as directly secured by an interest in an installment obligation to the extent an arrangement allows the taxpayer to satisfy all or a portion of the indebtedness with the installment obligation.".

(c) EFFECTIVE DATE.—The amendments made by this section shall apply to sales or other dispositions occurring on or after the date of the enactment of this Act.

SEC. 810. INCLUSION OF CERTAIN VACCINES AGAINST STREPTOCOCCUS PNEUMONIAE TO LIST OF TAXABLE VACCINES.

(a) IN GENERAL.—Section 4132(a)(1) of the Internal Revenue Code of 1986 (defining taxable vaccine) is amended by adding at the end the following new subparagraph:

"(L) Any conjugate vaccine against streptococcus pneumoniae.".

(b) EFFECTIVE DATE.—

(1) SALES.—The amendment made by this section shall apply to vaccine sales beginning on the day after the date on which the Centers for Disease Control makes a final recommendation for routine administration to children of any conjugate vaccine against streptococcus pneumoniae.

(2) DELIVERIES.—For purposes of paragraph (1), in the case of sales on or before the date described in such paragraph for which delivery is made after such date, the delivery date shall be considered the sale date.

TITLE IX—MISCELLANEOUS PROVISIONS

SEC. 901. MEDICARE COMPETITIVE PRICING DEMONSTRATION PROJECT.

(a) FINDING.—The Senate finds that implementing competitive pricing in the medicare program under title XVIII of the Social Security Act is an important goal.

(b) PROHIBITION ON IMPLEMENTATION OF PROJECT IN CERTAIN AREAS.—Notwithstanding subsection (b) of section 4011 of the Balanced Budget Act of 1997 (Public Law 105–33)), the Secretary of Health and Human Services may not implement the Medicare Competitive Pricing Demonstration Project (operated by the Secretary of Health and Human Services pursuant to such section) in Kansas City, Missouri or Kansas City, Kansas, or in any area in Arizona.

(c) MORATORIUM ON IMPLEMENTATION OF PROJECT IN ANY AREA UNTIL JANUARY, 1, 2001.—Notwithstanding any provision of section 4011 of the Balanced Budget Act of 1997 (Public Law 105–33)), the Secretary of Health and Human Services may not implement the Medicare Competitive Pricing Demonstration Project in any area before January 1, 2001.

(d) STUDY AND REPORT TO CONGRESS.—

(1) STUDY.—The Secretary of Health and Human Services, in conjunction with the Competitive Pricing Advisory Committee, shall conduct a study on the different approaches of implementing the Medicare Competitive Pricing Demonstration Project on a voluntary basis.

(2) REPORT.—Not later than June 30, 2000, the Secretary of Health and Human Services shall submit a report to Congress which shall contain a detailed description of the study conducted under paragraph (1), together with the recommendations of the Secretary and the Competitive Pricing Advisory Committee regarding the implementation of the Medicare Competitive Pricing Demonstration Project.

Attest:

Secretary.

106TH CONGRESS
1ST SESSION

H. R. 2990

AMENDMENT

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